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## **The impact of auditory hallucinations on the caregiving relationship in psychosis**

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**Empirical Research Project**

**Systematic Review**

**Service- Related Project**

**Priya Kochuparampil**

**Thesis submitted in partial fulfilment of the degree of  
Doctor of Clinical Psychology**

**Department of Psychology  
Institute of Psychiatry, Psychology & Neuroscience  
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*Empirical Research Project*

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**The impact of auditory  
hallucinations on the caregiving  
relationship in psychosis**

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*Supervised by:*

*Dr Juliana Onwumere &*

*Dr Suzanne Jolley*

*“...And those who were **seen** dancing were thought to be insane  
by those who could not hear the music....”*

*- Friedrich Nietzsche*

## **Abstract**

### **Background**

Auditory verbal hallucinations are common symptoms in psychosis conditions and will be distressing and persistent for many people. Though we are developing an improved understanding of their presentation in service users, far less is known about their impact on informal carers.

### **Objectives**

This study examines whether the presence of auditory verbal hallucinations in service users uniquely influences carers' appraisals of caregiving and the illness, and impact on their affective functioning, coping style and experience of stigma.

### **Methods**

The study used a cross-sectional design. Carers ( $n = 52$ ) were recruited from dedicated carer services attached to psychosis community mental health teams. The sample included 26 carers of service users who hear voices, and 26 carers of service users who do not hear voices. Participants completed self-report measures on their experience of caregiving, illness beliefs, affective disturbance and avoidant coping.

### **Results**

Overall, 35 - 60% of carers reported clinical levels of affective disturbance. Higher levels of carer distress were associated with service user difficulties unrelated to psychosis symptomatology. In direct comparisons, carers of voice hearers perceived their relatives to have more severe symptoms of psychosis compared to carers of service users who do not hear voices. No other significant hypothesised differences were found between the groups. An unexpected finding was that carers of those who do not hear voices perceived a greater need to back up the service user compared to carers of those who hear voices.

## **Conclusions**

The findings support previous literature documenting elevated mood and stress related disorders in carers of people with psychosis. However they offer minimal support, in the current sample, for the hypotheses that auditory verbal hallucinations differentially impact upon carers' experiences, illness beliefs, affective states and levels of avoidant coping. The findings underscore the importance of a needs-based framework for improving carer interventions, over a specific approach for voice hearing. Clinical implications and areas for future research are discussed.



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# 1. Introduction

## 1.1 Psychosis

The term 'psychosis' refers to a range of unusual experiences characterised by changes in a person's thinking and perceptions – often clinically categorised under the diagnostic umbrella of schizophrenia-spectrum disorders, but also occurring in severe affective conditions and organic disorders (Cowen et al., 2012). According to the Diagnostic and Statistical Manual of Mental Disorders (5th edition, American Psychiatric Association 2013), a diagnosis of schizophrenia requires persistent occurrence of two of the five following symptoms: delusions, hallucinations, disorganised speech, disorganised behavior or catatonia, and negative symptoms such as diminished emotional expression and avolition (Tandon et al., 2013). In England alone, psychosis affects 4 in 1000 new people per year (Kirkbride et al., 2012), with lifetime prevalence rates estimated at 1% (Perälä et al., 2007). Rates of psychosis are significantly higher among men and those living in urban areas (McGrath et al., 2004) and in black and minority ethnic (BAME) groups in the United Kingdom (UK), especially Black Caribbean, Black African and South Asian communities (Fearon et al., 2006; Kirkbride et al., 2012).

The first onset of psychotic symptoms is typically seen in late adolescence and early adulthood (Kessler et al., 2007) with an often chronic course characterised by a mixed pattern of remission and recurrent psychotic episodes (Barbato, 1998; Rossler et al., 2005). In addition, the negative symptoms of psychosis impact upon cognitive abilities such as task orientation and problem solving, as well as social cognition (Couture et al., 2006; Green & Harvey, 2014). Schizophrenia is also associated with a 2-3 fold increased mortality risk compared to the general population, with suicide and varied comorbid somatic conditions highlighted as contributory factors (McGrath et al., 2008). Schizophrenia and psychosis can have far-reaching negative consequences for individuals, families and society, with the annual cost to the public estimated at £11.8 billion in England (Schizophrenia Commission, 2012).

On an individual level, psychosis is a highly stigmatised condition, with up to 87% of service users reporting experiences of stigma and discrimination (Schizophrenia Commission, 2012). Individuals with psychosis commonly report high levels of shame and social withdrawal associated with perceptions of a loss in social status (Birchwood et al., 2007). Social exclusion is high in psychosis groups, and reported rates of employment for those with persisting psychosis range from 10-20% (Marwaha and Johnson, 2004) to as low as 8% (Schizophrenia Commission, 2012). People with psychosis also tend to have small social networks (Gayer-Anderson & Morgan, 2013; Giacco et al., 2016) and experience fewer opportunities to become parents or have romantic relationships (Fleury et al., 2008). However, up to half of those with psychosis maintain close contact with informal carers (Kuipers, 2010), with higher levels reported during the early illness phases and amongst some minority ethnic groups (Addington et al., 2003; Parabiaghi et al., 2007; Guada et al 2009).

## **1.2 Impact of psychosis on carers**

The term 'carer' is used in this study to refer to unpaid family and friends providing support to a person with psychosis. Similar definitions of carers have been used in the wider literature (Kuipers et al., 2010; Schizophrenia Commission, 2012). Carers are typically parents or partners of the identified patient (Lauber et al., 2003, 2005) and predominantly female (Awad & Voruganti, 2008). Research has demonstrated that carers can be a 'positive resource' who play an important role in improving service user outcomes (e.g. reduced number of inpatient admissions), (Kuipers & Bebbington, 1985; Norman et al., 2005). Carers can be a vital source of social contact and support to people with psychosis (Lester et al., 2011; Parabiaghi et al 2007) and provide important functions including facilitating recovery and integration with the local community (McFarlane & Cook, 2007). Furthermore, a recent study found that family involvement at first episode of psychosis reduced mortality from unnatural causes by 90%, compared to those without family involvement (Revier et al., 2015). Research also suggests that service users value the support of family members (Lester et al 2011; MacDonald et al.,

2005), often welcoming the opportunity to have them more closely involved in their care (Askey et al. 2009). Due to the long-term and fluctuating course of psychosis conditions, caregiving often entails a sustained commitment to support patients with relapses and/or residual symptoms (Harrow et al., 2005).

Considerable research confirms that the adverse impact of psychosis can also extend to carer health and wellbeing. Carers report high levels of burden (Awad & Voruganti, 2008) and stress (Poon et al., 2016; Hayes et al 2015; Weller et al., 2015), which is particularly evident in the first episode (Boydell et al., 2014; Jansen et al., 2015). Independent of the health condition, elevated rates of common mental disorders have been observed in carers compared to non-carers and particularly those providing over 10 hours of care or more per week (Smith et al., 2014). More specifically in psychosis, over 40% of carers meet criteria for psychiatric morbidity (Hayes et al., 2015), with significant proportions reporting symptoms of post-traumatic stress disorder (PTSD) (Barton and Jackson, 2008; Kingston et al., 2015), depression (Addington et al., 2003; Hayes et al., 2015) and anxiety (Gupta et al., 2015). Reports of 'burnout' in informal carers (e.g. emotional exhaustion, depersonalization, reduced personal accomplishment) can be high – comparable to levels reported in psychiatric nurses (Angermeyer et al., 2006). Carers commonly experience a sense of loss for the relative they once knew and sorrow about unfulfilled expectations, with levels of grief similar to those following bereavement (Patterson et al., 2005). In addition, the caregiving literature suggests that high levels of carer criticism, hostility and over involvement towards the patient, commonly described using the term high 'Expressed Emotion' (*EE*; Brown and Rutter, 1966; Brown et al., 1972), are highly correlated with carer burden, poorer carer outcomes and avoidant coping (Bebbington & Kuipers, 1994; Kuipers et al., 2006; Raune et al., 2004).

Cognitive models of caregiving in psychosis (e.g. Kuipers, Onwumere and Bebbington, 2010) focus on the cognitive, emotional and behavioural responses of carers, and seek to explain how such responses influence caregiving experiences and impact patients' wellbeing. Based on a review of the evidence base, Kuipers et al. (2010) highlight that key factors influencing

carers' outcomes are the attributions they report about the patient's difficulties (Barrowclough & Hooley, 2003; Hooley 1985) and appraisals about the impact of the illness and their own coping resources, rather than the apparent severity of the problems per se (Lazarus & Folkman, 1984; Leventhal et al., 1984). In their cognitive model, Kuipers et al. (2010) differentiate between different styles of caregiving based on positive and negative caregiving relationships. This model suggests that carers with high levels of patient criticism and hostility are more likely to appraise the patient's difficulties as controllable by the patient ('responsibility' attributions), and therefore something the patient can switch on and off at will. In turn, such attributions are hypothesised to exacerbate patient stress or decrease patients' sense of self-worth (Barrowclough & Hooley, 2003). In contrast, carers exhibiting higher levels of emotional overinvolvement are more likely to report self-blaming attributions and perceive their relative as not having any control over or responsibility for the illness and related behaviours. There is an overemphasis on the need to protect the patient from any difficulties. On the other hand, 'survivor appraisals', which attribute less responsibility to the patient for negative events and more responsibility for positive events, are more likely to be made by low EE carers (Grice et al., 2009). The model highlights that when carers do not perceive target behavior as under the control of the patient, they tend to be less critical and respond with greater levels of warmth.

Additionally, the model highlights other important factors contributing to carer functioning. For instance, the illness-related stigma that can be associated with having a relative with psychosis, can contribute to shame and social isolation. Carers in psychosis are ten times more likely to be socially isolated compared to non-caregiving peers (Hayes et al., 2015), and report significantly smaller social networks than carers of people with other long-term conditions (Magliano et al., 2006). Stigma reported by carers has been associated with having supernatural explanations of mental illness (Girma et al., 2014) and less mainstream/dual beliefs about causal processes and treatments. The Kuipers et al. (2010) model also emphasises the association between burden of care and less adaptive (i.e. avoidant) coping styles. These are invariably emotion-focused approaches to coping "*characterised by 'hoping problems will*

*go away' ”* (p.260). Avoidant coping is significantly positively associated with carer distress (Dyck et al., 1999; Onwumere et al., 2011), particularly in circumstances when more problem-focused coping would be helpful.

### **1.3 Symptom-oriented approach: Auditory Hallucinations in Psychosis**

In the last 10-15 years, there has been a move in psychosis-related research to focus on individual symptoms rather than categorical diagnostic labels such as 'schizophrenia' (e.g. Bentall et al., 2014; Trower et al., 2004). The focus has been on specific symptom presentations, with a growing literature on the individual experience of delusions of different types (Garety & Freeman 2013, Iyassu et al. 2014), hallucinations (Beaven & Read, 2010; Howard et al., 2013; Jenner et al., 2008; McCarthy-Jones et al., 2014), negative symptoms (Klingberg et al. 2011, Mairs et al. 2012) and thought interference (Linney & Peters 2007). Of these symptom groups, hallucinations are considered to represent a particularly complex experience, with a range of causal pathways and psychological mechanisms reported to play a role (e.g. Hunter et al., 2004; Seal et al., 2004; Jones, 2010).

A hallucination can be defined as a “sensory experience, which occurs in the absence of corresponding external stimulation of the relevant sensory organ, has a sufficient sense of reality to resemble a veridical perception, over which the subject does not feel s/he has direct and voluntary control and which occurs in the awake state” (Anthony, 2004). Hallucinations in the auditory modality are common among individuals with psychosis (Owens et al., 1989), with studies indicating prevalence rates between 40-60% in patients with schizophrenia (Slade & Bentall, 1988; Nayani & David, 1996) and persistence, despite pharmacological treatments (Carter et al., 1996; Pantellis & Barnes, 1996). Auditory verbal hallucinations (AVH) represent a distinct experience in psychosis with diverse manifestations: some experience voices commenting on the individual's thoughts, words and actions, issuing commands and/or discussing the individual amongst themselves (Romme, 1998; Slade and Bentall, 1988). Furthermore, evidence suggests people can experience



significant distress in relation to AVH, often mediated by their appraisals of the voice(s) (Thomas et al., 2015; Morrison, 1998).

### ***Carers and the symptom-orientated approach***

Extending the symptom-oriented approach to carers in psychosis, it is important to recognise that many carers of people with psychosis deal with a diverse range of unusual symptoms, including voices or other hallucinations, delusional or suspicious thinking (Onwumere et al., 2008) and embarrassing or violent behaviours (Kuipers, 2010; Onwumere et al., 2014). In addition, recent studies suggest a potential interplay between specific symptom presentations in people with psychosis and particular carer characteristics. For instance, levels of belief flexibility in service users with delusions vary according to the presence and quality of caregiving relationships (Jolley et al., 2014). Moreover, particular symptoms in people with psychosis have been linked with significantly higher levels of carer distress and burden, including disorganisation symptoms (Wolthaus et al., 2002), social withdrawal and inactivity associated with the negative symptoms of psychosis (Ukpong, 2006) and unpredictable disruptive behaviour (Kuipers, 2006, 2010). Furthermore, Onwumere et al. (2016) report that carers of people with delusions reported a poor understanding about their relative's delusions and a fear of delusion-driven behaviours. They found that caregiving relationships seemed fraught, carers tried to conceal the extent of their caregiving difficulties, and the development of their coping strategies seemed an ongoing process of trial and error. To date, much of the symptom-specific focus in the caregiving literature has tended to centre on negative symptoms and delusions, with a lack of data on understanding carer experiences related to AVH.

Identifying the pathways by which AVH may impact on the caregiving relationship is particularly relevant as emerging evidence suggests that cognitive based interventions for voice hearing can be readily adapted into a successful group programme for carers of patients coping with distressing voices. A relatively recent study in Australia successfully piloted such an approach, working jointly with carers and voice hearers to specifically target

AVH, which are known to cause particular difficulties in the caregiving relationship and are challenging for carers to understand and manage (Maxwell et al., 2012). Similarly, an approach specifically targeting medication-resistant AVH has been piloted with families in the Netherlands. Hallucination-focused integrative treatment (HIT, Jenner et al., 2001, 2013) incorporates psychoeducation, motivational interventions, coping skills enhancement, CBT, and operant conditioning within a single-family or multi-family format (Jenner et al., 2004, 2006). National clinical guidelines for psychosis (National Institute for Health and Care Excellence, NICE, 2014) stipulate that carers are offered support in their own right, including information to help them understand the illness. However, more research is required in order to individualise support for carers based on service user symptomatology. A more in-depth understanding of how AVH impact on important carer outcomes would help tailor family-based interventions in a symptom-focused way, so as to help carers specifically with AVH and enable them to better support service users who hear voices.

## **1.4 Rationale for current study**

AVH represent a distinct, complex and often treatment-resistant symptom in psychosis conditions, which can often be associated with distress and impaired functioning in patients. Given the limited understanding of the interplay between AVH and carer experiences and wellbeing, and in the context of the Kuipers et al (2010) model of caregiving responses, this study seeks to examine the extent to which AVH impact upon caregiving appraisals, illness beliefs, affect and coping.

AVH may impact on caregiving in unique ways. Previous work suggests an association between AVH and reports of carer burden (Kuipers et al., 2000) and perceived stigma (Ritsher et al., 2004). It might be argued that this is due to AVH being a more 'obvious' or visible symptom compared to other positive symptoms in psychosis such as delusional beliefs (e.g. Donaldson et al., 1998; Vilhauer, 2014). In addition, AVH are often pathologised and seen as a defining feature of being poorly (Longden et al., 2012), which could have an

impact not only on the stigma associated with having a relative who hears voices, but also on the carer's appraisals of their relative's illness.

Given what is already known about voice hearing, it is possible that AVH may give rise to subsequent problems in carers' interactions with service users. For example, interactions may be affected through the distraction voices may engender in service users and possibly through debates about their origins and cause. The literature already confirms that many people with voice hearing experiences can express beliefs about the origin and assumed identities of their voices which might include family members (Nayani & David, 1996). Furthermore, voice characteristics and content may render voices indistinguishable from carer communications for service users who hear voices. Carers might have to frequently remind their relative that they are not part of their voices or cannot hear them, which might impact on their caregiving experiences. It is possible that these additional challenges might leave carers to appraise their caregiving experiences in a more negative or less positive manner. This increased burden can also influence carers' coping styles, as highlighted in the literature. It seems plausible that the persistence and complexities of the voice-hearing experiences in many service users might increase carer burden, leading them to resort to more avoidant coping styles. Thus, AVH could have wide-ranging negative impacts on carers' wellbeing and functioning.

The present study aims to extend our understanding of the diverse experiences of a subgroup of carers in terms of caregiving and stigma, appraisals of the illness, extent of avoidant coping, affective disturbance and positive wellbeing. Embedded within the Kuipers et al. (2010) cognitive model of caregiving responses, the study aims to explore the impact of AVH on caregiving experiences and affect. Specifically, it will compare outcomes on key measures of functioning between carers of service users who hear voices with carers of service users who do not hear voices.

## **1.5 Hypotheses**

The main hypotheses in the present study were that in comparison to carers of service users who do not hear voices, carers of voices hearers would report:

- 1.) a more negative experience of caregiving (burden) and greater levels of stigma
- 2.) more negative illness beliefs
- 3.) greater affective disturbance, as manifested by higher levels of depression, anxiety and psychological distress and lower levels of positive wellbeing
- 4.) greater use of avoidant coping strategies

## **2. Methods**

The study employed a cross-sectional design using quantitative measures. The study was approved by the National Research Ethics Service (NRES) Committee – London Bridge (REC Reference: 15/LO/0680) and the KCL/SLaM Research & Development (Reference: R&D2015/083), (see Appendix 1).

### **2.1 Sample**

Participants were carers of service users with established schizophrenia spectrum diagnoses. Recruitment took place in two specialist community mental health teams (CMHTs) for working age adults with psychosis (18-65), in two inner city South London boroughs. Study inclusion criteria were those:

- a) currently in a self-defined caregiving role for a service user receiving care in the aforementioned CMHTs
- b) having weekly contact with service users
- c) aged 18 years old or above

The exclusion criterion were:

- a) carers who themselves have a known diagnosis of severe mental illness and are currently unwell
- b) carers with learning disabilities or any diagnosis of dementia
- c) carers with insufficient command of English to participate in the assessment procedures (as it was not possible to provide interpreters and translated versions of the measures were not available).

## **2.2 Power calculations**

To the author's knowledge, this was the first study designed to differentiate carer outcomes on the target areas of interest between carers based on the symptoms of those they care for. Therefore, it was not possible for current literature to inform an exact power calculation. However, a power calculation conducted using the software package G\*Power (Faul & Erdfelder 1992) showed that for between group comparisons, a minimum sample size of 26 carers per group would have 80% power to detect large effect sizes (0.8 and above,  $\alpha = 0.05$ ). This is also in line with recommendations for parametric tests that suggest results can usually be regarded as robust with a sample size of over 25 participants in each group (Howell, 2007).

## **2.3 Recruitment**

Potential participants were identified in collaboration with dedicated carer support services established in 2013 as part of routine care in secondary care community mental health teams in the 'Promoting Recovery' pathway, based in the London boroughs of Lambeth and Southwark. There are four locality teams per borough, each with an approximate caseload of 200-250 service users with established psychosis (Allen et al., in press). The carer support services employ one assistant psychologist per borough, supervised by senior Clinical

Psychologists. Carers self-referred or were referred by clinicians at these CMHTs to the carer support services, where assistant psychologists made initial contact with carers and provided information about carer interventions being run in the service, as well as details of the present study.

## **2.4 Procedure**

All carers who expressed an interest in the study were subsequently contacted to arrange a face-to-face assessment at a mutually convenient time. Participants were given information sheets with details of the study and their participation requirements. All participants who gave their verbal consent to take part were also required to sign a participant consent form (See appendix 2 for copies). Assessments were carried out either at the CMHT bases or at the research base - King's College London. The researcher remained on hand to support completion: most carers requested assistance in completing the measures. Assessments typically lasted between 1–2 hours, depending on the extent to which carers elucidated their responses on the measures.

## **2.5 Assessment measures**

All carers completed a form which recorded socio-demographic details including age, gender, marital status, employment status, relationship to the service user, whether they were living with the service user and hours of weekly contact with the service user. Participants were asked to complete a small battery of self-report measures that assessed individual appraisal about caregiving, their illness understanding and affective functioning (see Appendix 3 for copies of all measures).

### **2.5.1 Carer Appraisals of service user symptoms and caregiving**

#### **Carer Experience of Symptoms-Questionnaire (CES-Q)**

To evaluate carer appraisals of service user symptomatology, carers completed a 7-item measure. The measure requires carers to read through different statements about psychosis symptomatology (e.g. delusions,

hallucinations, low motivation) and rate whether the service user is affected by each difficulty and if so, the extent to which the carer is distressed by the symptom. Distress ratings range from 0-10, with scores of 10 indicating the highest levels of distress about a symptom. The CES-Q was purposively designed for the carer support services in the promoting recovery CMHTs as a simple and brief tool to determine the type of patient symptoms that carers are exposed to and which they are upset by. It was used in the current study to differentiate carers of service users with current voice hearing experiences from carers of service users who do not hear voices, and to indicate which service user symptoms were most distressing to carers.

### **The Experiences of Caregiving Inventory (ECI, Szmukler et al., 1996)**

The ECI is recognised as a 'gold standard' measure to assess carer appraisals of the experience of caring for someone with a severe mental illness (e.g. Grover et al., 2012; Harvey et al., 2001). It is a 66-item measure, comprising 10 subscales: eight negative (i.e. difficult behaviours, negative symptoms, stigma, effects on the family, need to provide back-up, problems with services, dependency and loss) and two positive (i.e. good aspects of the relationship and rewarding personal experiences). Carers rate how often they have thought about the issue presented in each item over the last month on a five-point Likert scale. The 52 items of the negative subscale have a maximum score of 208, and the 14 items of the positive subscale have a maximum score of 56. The ECI yields individual subscale scores, as well as an overall negative and positive summary subscale scores. The ECI has good construct validity and reliability (Joyce, Leese, & Szmukler, 2000; Szmukler et al., 1996). In the current study, the internal consistency of the negative ECI was  $\alpha=.93$  and the positive ECI was  $\alpha=.78$ .

### **Brief Illness Perception Questionnaire (B-IPQ, Broadbent, Petrie, Main, & Weinman, 2006)**

The B-IPQ assesses appraisals about an illness along 8 dimensions: consequences (i.e. the effect of the illness on the carer), timeline (i.e. how long the illness will continue), personal control (i.e. extent to which service users

can control their symptoms), treatment control (i.e. how effective treatments can be), identity (i.e. the extent to which symptoms are experienced by the service user), illness concern (i.e. how concerned the carer is about the illness), coherence (the carer's understanding of the illness), and emotional representation (i.e. the emotional impact of the illness on the carer). Each dimension is assessed with a single-item and rated on a scale from 0 to 10. To reflect that the informant was a carer of the service user, and consistent with other studies that have used variations of the B-IPQ with carers (e.g. Barrowclough et al., 2001; Onwumere et al., 2008), the wording of the original B-IPQ was slightly revised. For example, "*How long do you think his/her problems/illness will continue?*" Total scores range from 0-80, with higher scores indicating higher overall threat perceived. The B-IPQ has good concurrent validity and test-retest reliability (Broadbent et al., 2006). The internal consistency of the B-IPQ in the current study was  $\alpha=.56$

### **2.5.2 Carer Affective functioning**

#### **Clinical Outcomes in Routine Evaluation scale-10 (CORE-10, Barkham et al., 2013)**

The CORE is a self-report questionnaire which measures current psychological global distress. The CORE-10 is an abbreviated 10-item scale derived from the original 34-item CORE-OM (CORE-Outcome Measure), which was developed for use in routine clinical practice. It assesses four domains: wellbeing, problems/symptoms, functioning and risk. Responders rate how they have felt in the last week on a scale of 0 (not at all) to 4 (most/all of the time), with higher scores indicating higher psychological distress. Total scores range from 0-40, with scores of 11 or above indicative of clinically significant psychological distress. The CORE has been validated with clinical and non-clinical samples, and is considered a useful outcome measure due to sound psychometric properties (Evans et al., 2002). It has good sensitivity to change when used to measure psychological distress of carers in psychosis following carer interventions (Roddy et al., 2015). The internal consistency of the CORE-10 in the current sample was  $\alpha=.78$ .



**The Patient Health Questionnaire (PHQ-9, Kroenke, Spitzer & Williams, 2002)**

This is the self-administered depression module of the Primary Care Evaluation of Mental Disorders (PRIME-MD). It comprises nine statements corresponding to each of the 9 DSM-IV criteria for diagnosing depressive disorders. Respondents are asked to rate the extent to which each of the symptoms have affected them in the previous two weeks, ranging from 0 (not at all) to 3 (nearly every day). The PHQ-9 has been shown to be a reliable and valid measure of depression severity (Kroenke et al., 2002), with good sensitivity to change (Löwe et al., 2004). Total scores range from 0-27 and are categorised by severity of depression, with varying cut-offs for minimal (1-4), mild (5-9), moderate (10-14), moderately severe (15-19) and severe (20-27) depression. A score of 10 or above meets criteria for clinical caseness. The internal consistency of the PHQ-9 in the current study was  $\alpha=.85$ .

**Generalised Anxiety Disorder Scale (GAD-7, Spitzer, Kroenke, Williams, & Löwe, 2006)**

This 7-item scale requires rating the occurrence of seven anxiety symptoms over the previous two weeks using a four-point scale, ranging from 0 (not at all) to 3 (nearly every day). Total scores range from 0-21 which can be categorised by severity: minimal/no anxiety (0-4), mild (5-9), moderate (10-14), or severe (15-21). A score of 8 or above meets criteria for clinical caseness. Studies validating the GAD in clinical and non-clinical populations have shown the GAD-7 has criterion, construct, factorial, and procedural validity and is a reliable measure of anxiety (e.g. Spitzer et al., 2006; Löwe et al., 2004; Ruiz et al., 2011). The internal consistency of the GAD-7 in the current study was  $\alpha=.84$ .

**The Warwick-Edinburgh Mental Well-being Scale (WEMWBS, Tennant et al., 2007)**

This is a 14-item measure of positive mental wellbeing covering subjective wellbeing and psychological functioning. Statements focusing on positive aspects of mental health are rated over the last two weeks from 1 (none of the time) to 5 (all of the time). Scores range from 14–70, with higher scores

indicating a higher level of positive mental wellbeing. The UK general population adult mean has been recorded as 50.7 (Brown and Janmohamed 2008). The WEMWBS has good validity and reliability and has demonstrated good sensitivity to change in evaluations of varied interventions and with diverse populations (e.g. Stewart-Brown et al., 2011; Maheswaran et al., 2012). The internal consistency was high in the present sample,  $\alpha=.93$ .

### **Brief COPE- Avoidant scales (Carver, 1997)**

The COPE (Carver, Scheier & Weintraub, 1989) assesses theoretically derived coping styles. An abbreviated version—the Brief COPE (Carver, 1997) comprises 14 sub-scales with 2 items each: 8 focusing on adaptive coping strategies and 6 measuring maladaptive coping. Factor analytic studies have shown that wider dimensions of coping can be derived from the Brief COPE, including active / positive coping, seeking support and avoidance / disengagement (see review by Kapsou et al., 2010). In keeping with previous research (Kuipers et al., 2006; Onwumere et al., 2011; Kingston et al. 2015), an ‘avoidant’ coping style was derived by combining items from 4 subscales: behavioural disengagement, self-distraction, substance use and denial, to create an 8-item Brief COPE – Avoidant scale.) The other two subscales suggestive of less adaptive coping styles are venting and self-blame. The Brief COPE has good psychometric properties (Carver, 1997) and is effective in predicting clinically relevant outcomes such as anxiety, as well as negative and positive affect (e.g. Lowe et al., 2000). Total scores on the COPE-Avoidant scale range from 0-24, with higher scores suggesting higher levels of avoidant coping. In the current study, the internal consistency of the brief COPE – Avoidant Scale was  $\alpha=.53$ .

## **2.6 Statistical Analyses**

Statistical analysis was carried out using the Statistical Package for the Social Sciences (SPSS) software, version 23 for Windows (IBM, 2013). Descriptive statistics were used to summarise demographic characteristics. Independent-samples t-tests were carried out to examine any differences between groups in

age of participants and hours of contact with service users (continuous variables). No analyses were carried out on categorical variables such as ethnicity, current partnership status, employment status, and relationship to the service user, as these variables comprised many sub-categories with very small sample sizes, resulting in insufficient power to detect significant differences between the groups.

All data were checked for normal distribution using Shapiro-Wilk tests and inspecting histograms, boxplots and Q-Q plots. Two variables violated the Shapiro-Wilk test of normality ( $p < .05$ ). Ratings made by carers of voice hearers on the GAD-7 ( $p = .01$ ) and the PHQ-9 ( $p = .01$ ) were not normally distributed. Further examination of histograms and Q-Q plots revealed that the data were not heavily skewed. Furthermore, the standard deviations of each measure were similar in the two groups, indicating no large discrepancy in variance. However, boxplots indicated an outlier for the PHQ-9. When this outlier was omitted, the data were normally distributed ( $p = .15$ ).

Independent-samples t-tests were conducted to examine whether carers of service users who hear voices (shortened to **CVH**: carers of voice hearers) differed from carers of service users with psychosis who do not hear voices (shortened to **CNVH**: carer of non-voice hearers) on target outcomes. For data that were not normally distributed, non-parametric bootstrap tests were used to confirm that results of the independent-samples t-tests did not change. In addition, analyses for the PHQ-9 were re-run without the outlier to check whether this changed the results.

Effect sizes were computed using the formula for Cohen's 'd':

$$d = \frac{M_1 - M_2}{SD_{pooled}}$$

Twelve carers did not complete the entire battery of measures, typically because they could not do so in one assessment session and did not attend a follow-up session. This resulted in missing sets of data on each measure. To

determine whether there was any pattern in the missing data, chi-square tests were carried out on the following categorical variables: gender, whether participants were carers of voice hearers, whether they lived with the service user and whether they cared for anyone else. Any pattern in non-response corresponding to carers' age and hours of contact with service users was examined with independent-samples t-tests. These two variables had similar variance within completer and non-completer groups, but the age variable was not normally distributed among completers. However, examination of histograms and Q-Q plots revealed three 'younger' outliers among the completers; the data was otherwise not heavily skewed. As parametric tests are considered 'robust' to violations of normality (Howell, 2007), independent samples-tests were used. There was no indication there was a pattern in the missing data, so it was assumed missing completely at random. Hence, including the data of non-completers in the study would not result in any bias.

The reduced sample size due to missing data in each group, reduced power to detect moderate-large effects. No corrections for multiple testing were carried out as this would further reduce power to detect differences between groups. In addition, the clear pre-specification of each hypothesis and limited number of planned tests reduces the multiplicity problem, i.e. for three of the four key hypotheses, the *a priori* analysis plan was to test each tightly defined hypothesis by means of one key significance test. However, for the hypothesis regarding levels of affective disturbance in carers, four tests of significance were used to investigate the difference between groups on four variables related to the hypothesis. In this case, it was acknowledged that any significant findings arising from multiple tests for a single hypothesis might be false positives due to multiple testing (Bender & Lange, 2001).

### **3. Results**

A total of 52 carers were assessed for the study, comprising 26 participants in the CVH (carers of voice hearers) group and 26 in the CNVH (carers of non-voice hearers) group. Data was incomplete for 12 participants, including 8

CVH and 4 CNVH. The mean age of non-completers was 44.92 years ( $SD=12.62$ ) and 53.65 years in completers ( $SD= 16.49$ ).

## 3.1 Demographics

### 3.1.1 Carer demographics

Of the 52 participants, over two thirds were female (69.2%,  $n =36$ ), with equal gender proportions in each group (8 males, 31%; 18 females, 69%). The mean age of all participants was 51.63 years ( $SD=16$  years; range=18-84 years). No significant group differences were observed for age,  $t(50) =-.03$ ,  $p= .98$ ); (for CVH:  $M=51.69$  years,  $SD = 17.10$  years, range = 18-84 years, while for CNVH:  $M=51.58$  years,  $SD = 15.16$  years, range = 18-83 years). Approximately half the sample was aged between 40-60 years, comprising 12 participants (46.2%) in CVH, and 14 participants (53.8%) in CNVH. The age range of participants is presented in Table 1.

*Table 1. Age of participants*

<i>Age</i>	<i>CVH n(%)</i>	<i>CNVH n(%)</i>	<i>Total n(%)</i>
18-39	6 (23%)	4 (15.4)	10 (19.2)
40-60	12 (46.2)	14 (53.8)	26 (50)
> 60	8 (30.8)	8 (30.8)	16 (30.8)

The overall sample was ethnically diverse, with more than two-thirds stemming from black and minority ethnic (BAME) backgrounds (71.2%). The CVH sample had double the number of white participants ( $n=10$ , 38.5%) than CNVH ( $n=5$ , 19.2%), whereas CNVH had more people from other diverse ethnic backgrounds ( $n=8$ , 30.8%) compared to CVH ( $n=2$ , 7.7%). The ethnic background of participants is presented in Table 2.

*Table 2. Ethnicity of participants*

<i>Ethnicity</i>	<i>CVH n(%)</i>	<i>CNVH n (%)</i>	<i>Total n(%)</i>
White	10 (38.5)	5 (19.2)	15 (28.8)
Black Caribbean	4 (15.4)	6 (23.1)	10 (19.2)

Black African	9 (34.6)	6 (23.1)	15 (28.8)
Indian	1 (3.8)	1 (3.8)	2 (38)
Other	2 (7.7)	8 (30.8)	10 (19.2)

The current partnership status of participants is described in Table 3. A notable proportion of both groups was single.

*Table 3. Current partnership status of participants*

<i>Marital Status</i>	<b>CVH</b> <i>n(%)</i>	<b>CNVH</b> <i>n (%)</i>	<b>Total</b> <i>n(%)</i>
Single	10 (38.5)	14 (53.8)	24 (46.2)
Married	9 (34.6)	5 (19.2)	14 (26.9)
Cohabiting	1 (3.8)	1 (3.8)	2 (3.8)
Divorced/separated	3 (11.5)	2 (7.7)	5 (9.6)
Widowed	2 (7.7)	4 (15.4)	6 (11.5)
Other	1 (3.8)	-	1 (1.9)

The employment status of participants is presented in Table 4. CNVH had nearly three times the number of fully-employed participants (n=11, 42.3%) as CVH (n=4, 15.4%). Overall, one quarter of participants were retirees (23.1%).

*Table 4. Employment status of participants*

<i>Employment status</i>	<b>CVH</b> <i>n(%)</i>	<b>CNVH</b> <i>n (%)</i>	<b>Total</b> <i>n(%)</i>
Employed full-time	4 (15.4)	11 (42.3)	15 (28.8)
Employed part-time	3 (11.5)	2 (7.7)	5 (9.6)
Unemployed	9 (34.6)	6 (23.1)	15 (28.8)
Housewife/husband	1 (3.8)	-	1 (1.9)
Student	2 (7.7)	1 (3.8)	3 (5.8)
Retired	7 (26.9)	5 (19.2)	12 (23.1)
Other	-	1 (3.8)	1 (1.9)

### 3.1.2 Carer relationship to service users

In both groups, mothers comprised one third of the carer relationships. Similar rates were observed for partners. The CVH sample did not contain any siblings or fathers of service users whereas CNVH did not contain any friends.

*Table 5. Relationship to service user*

<i>Relationship to Service User</i>	<b>CVH</b> <i>n (%)</i>	<b>CNVH</b> <i>n (%)</i>	<b>Total</b> <i>n (%)</i>
Mother	8 (30.8)	9 (34.6)	17 (32.7)
Father	-	2 (7.7)	2 (3.8)
Partner	8 (30.8)	7 (26.9)	15 (28.8)
Daughter	4 (15.4)	2 (7.7)	6 (11.5)
Son	2 (7.7)	1 (3.8)	3 (5.8)
Sister	-	1 (3.8)	1 (1.9)
Brother	-	3 (11.5)	3 (5.8)
Friend	2 (7.7)	-	2 (3.8)
Other	1 (3.8)	1 (3.8)	2 (3.8)

Nearly two-thirds of CVH lived with service users ( $n=18$ , 70%), whereas only half the CNVH lived with the service users they cared for ( $n= 13$ , 50%). Overall, a third of carers reported that they cared for other people in addition to the service user ( $n=17$ , 32.7%), including 11 CVH (42.3%) and 6 CNVH (23.1%). All carers had regular contact with service users, averaging 21.2 contact hours per week ( $SD=39.3$ ; range= 3 -168). CVH averaged more hours per week with service users ( $M=63.58$ ,  $SD=78.48$ ), than CNVH ( $M=44.21$ ,  $SD=51.37$ ). The mean difference between groups (19.37 hours, 95% CI [56.46, 17.73]) was not significant;  $t(43) = -1.05$ ,  $p= .30$ .

### 3.2 Carer distress in relation to specific service user symptoms

Carers rated their distress in relation to specific service user symptomatology on the CES-Q. Distress ratings are provided in Table 6, corresponding to those

carers in each group, and overall, who identified that these specific symptoms were experienced by the service user.

*Table 6. Carer-rated symptomatology in service users*

<i>Service User Symptoms</i>	<i>No. of carers rating symptom as present</i>	<i>Carer-rated distress at each symptom</i>		
	<b>Total <i>n</i> (%)</b>	<b>CVH</b>	<b>CNVH</b>	<b>Overall Mean (S.D.)</b>
<b>Delusions</b>	25 (48%)	19	6	6.76 (3.23)
<b>Auditory Hallucinations</b>	25 (50%)	25	0	7.48 (3.12)
<b>Low mood</b>	37 (71%)	20	17	6.89 (2.40)
<b>Low motivation</b>	29 (56%)	14	15	7.66 (2.72)
<b>Poor self-care</b>	27 (52%)	15	12	6.7 (2.89)
<b>Other problems</b>	24 (46%)	14	10	8.17 (2.28)

Approximately three times as many CVH participants reported the presence of delusions in service users compared to CNVH. The highest distress ratings for both groups was in relation to 'other problems experienced by the service user' ( $M > 7.9$  [out of 10]), indicating that maximum carer distress was associated with service user difficulties other than the positive and negative symptoms of psychosis. The commonly reported 'other problems' by carers in the present study included eating problems, financial problems, coping with dependent children, alcoholism, anxiety around travelling, gambling, self-harm, sleeping problems and physical disability.



### 3.3. Hypotheses testing

Means and standard deviations for the two groups, along with the mean difference between groups, 95% confidence intervals (*CI*), t-test statistic (*t*), degrees of freedom (*df*) and the statistical significance of the difference between groups (*p*), are reported for each variable in Table 7.

*Table 7. Mean Differences between CVH and CNVH*

Variable	Mean (SD)		Mean difference (95% CI)	<i>t</i> (df)	<i>p</i>
	<b>CVH</b>	<b>CNVH</b>			
<b><i>ECI Negative subscale</i></b>	85.36 (34.99)	93.96 (31.45)	-8.60 (-27.5, 10.3)	-.91 (48)	.37
1.ECI Stigma	7.20 (5.39)	7.68 (4.41)	-.48 (-3.3, 2.3)	-.35 (48)	.73
2.ECI Difficult behaviours	14.24 (8.16)	13.90 (8.8)	.34 (-4.4, 5.1)	.15 (48)	.89
3.ECI Negative symptoms	11.84 (6.77)	13.60 (6.08)	-1.76 (-5.4, 1.9)	-.97 (48)	.34
4. ECI Effects on family	10.08 (7.6)	11.68 (5.03)	-1.60 (-5.2, 2.1)	-.88 (48)	.39
5. ECI Need for back-up	10.56 (4.64)	13.51 (5.0)	-2.95 (-5.7, -.2)	-2.16 (48)	.04
6. ECI Problems with services	10.08 (7.29)	10.31 (6.02)	-.23 (-4.0, 3.6)	-.12 (48)	.90
7. ECI Dependency	10.92 (4.44)	11.44 (3.68)	-.52 (-2.8, 1.8)	-.45 (48)	.65
8. ECI Loss	10.44 (5.77)	11.84 (4.62)	-1.4 (-4.4, 1.6)	-.95 (48)	.35
<b><i>ECI Positive subscale</i></b>	31.16 (9.96)	31.37 (8.44)	-.21 (-5.5, 5.0)	-.08 (48)	.94
1. ECI Good aspects of relationship	12.88 (5.2)	13.39 (4.57)	-.51 (-3.3, 2.3)	-.37 (48)	.72
2. ECI Rewarding personal experiences	18.28 (6.05)	17.98 (5.39)	.30 (-3.0, 3.6)	.19 (48)	.85
<b><i>B-IPQ total</i></b>	53.23 (10.36)	50.17 (10.34)	3.05 (-3.2, 9.3)	.99 (43)	.33
1. IPQ Consequences	6.39 (2.92)	7.57 (2.21)	-1.17 (.2.7, .37)	1.54 (44)	.13
2.IPQ Timeline	9.13 (1.69)	8.39 (2.02)	.74 (-.4, 1.8)	1.35 (44)	.18
3.IPQ Identity	7.59 (2.24)	6.09 (2.73)	1.5 (-.001, 3.0)	2.02 (43)	.05
4.IPQ Illness concern	8.00 (2.81)	8.35 (2.48)	-.35 (-1.9, 1.2)	-.45 (44)	.66
5.IPQ Emotional representation	8.00 (2.47)	7.91 (2.52)	.09 (-1.4, 1.6)	.12 (44)	.91
6. IPQ Treatment control	6.17 (3.14)	6.65 (2.81)	-.48 (-2.2, 1.3)	-.54 (44)	.59
7. IPQ Personal control	3.30 (2.91)	4.13 (3.24)	-.83 (-2.7, 1.0)	-.91 (44)	.37
8. IPQ Coherence	6.61 (2.64)	7.35 (2.39)	-.74 (-2.2, .76)	-1.0 (44)	.33
<b><i>CORE-10</i></b>	11.40 (6.82)	13.77 (6.32)	-2.37 (-6.1, 1.3)	-1.29 (49)	.20
<b><i>GAD-7</i></b>	6.30 (5.33)	7.56 (4.74)	-1.26 (-4.2, 1.7)	-.86 (46)	.39
<b><i>PHQ-9</i></b>	6.58 (5.19)	8.84 (6.58)	-2.26 (-5.7, 1.2)	-1.33 (47)	.19

<i>WEMWBS</i>	45.57 (12.23)	44.54 (9.59)	-1.03 (-7.3, 5.3)	-.33 (47)	.74
<i>Brief COPE- Avoidant</i>	6.96 (3.83)	7.13 (3.69)	-.17 (-2.4, 2.0)	-.15 (45)	.88
1.COPE Behavioural disengagement	2.09 (1.76)	1.83 (1.9)	.25 (-.8, 1.3)	.47 (45)	.64
2. COPE Self-distraction	3.48 (1.86)	3.71 (1.68)	-.23 (-1.3, .8)	-.45 (45)	.66
3. COPE Substance use	.57 (1.38)	.63 (1.13)	-.06 (-.8, .7)	-.16 (45)	.87
4. COPE Denial	.83 (1.19)	.96 (1.63)	-.13 (-.9, .7)	-.32 (45)	.75

### 3.3.1 Hypothesis 1: CVH report a more negative experience of caregiving (burden) and greater stigma compared to CNVH

No significant differences were found between the two groups on overall negative experience of caregiving (burden), as measured by the negative subscale score of the ECI, (mean difference= -8.60,  $p = .37$ ,  $d = -.26$ ). Moreover, mean scores were not in the expected direction: CVH ( $M=85.36$ ,  $SD=34.99$ ) reported a less negative experience of caregiving than CNVH ( $M=93.96$ ,  $SD=31.45$ ).

Closer inspection of the negative experiences indicated that CVH provided lower ratings on the 'Need for back-up' subscale ( $M=10.56$ ,  $SD=4.64$ ), than CNVH ( $M=13.51$ ,  $SD=5$ ); (mean difference = -2.95,  $p=.04$ ,  $d=-.61$ ). The effect size ( $d=.61$ ) exceeded Cohen's (1988) convention for a moderate effect ( $d = .5$ ).

In terms of stigma, as measured by the stigma subscale of the ECI, the mean difference ( $MD$ ) between groups was not significant ( $MD= -.48$ ,  $p=.73$ ,  $d= -.1$ ).

Further analyses revealed that CVH scores were not significantly different from CNVH on any other negative subscales of the ECI.

### 3.3.2 Hypothesis 2: CVH report more negative illness beliefs compared to CNVH

Comparisons between the two groups on their illness appraisals as measured by the B-IPQ total score, indicated that CVH held more negative perceptions of the service user's illness ( $M=53.23$ ,  $SD=10.36$ ) than CNVH ( $M=50.17$ ,

$SD=10.34$ ). However, the mean difference was not statistically significant ( $MD= 3.05$ ,  $p=.33$ ,  $d=.3$ ).

Further analyses of the 8 IPQ dimensions, indicated a significant difference in ratings on the 'IPQ-Identity' item. Mean ratings for CVH ( $M=7.59$ ,  $SD=2.24$ ) were significantly higher than CNVH ( $M=6.09$ ,  $SD=2.73$ ), ( $MD=1.5$ ,  $p=.05$ ,  $d=.6$ ). This suggests that CVH appraised service users as experiencing more severe symptoms of their illness.

**3.3.3 Hypothesis 3:** CVH report greater affective disturbance, as manifested by higher levels of depression, anxiety and psychological distress and lower levels of positive wellbeing compared to CNVH

Contrary to hypotheses, results indicated no significant differences between participant groups on levels of affect, stress indicators and positive wellbeing ( $p \geq .19$ ; see table 7 for details).

Mean scores on the CORE-10 indicated that CVH ( $M=11.4$ ,  $SD=6.82$ ) reported lower psychological distress than CNVH ( $M=13.77$ ,  $SD=6.32$ ). Mean GAD-7 scores were also lower for CVH ( $M=6.30$ ,  $SD=5.33$ ) than for CNVH ( $M=7.56$ ,  $SD=4.74$ ). Applying a non-parametric bootstrap test did not change the results. Similarly, mean scores on the PHQ-9 were lower for CVH ( $M=6.58$ ,  $SD=5.19$ ) than for CNVH ( $M=8.84$ ,  $SD=6.58$ ). Re-running the analysis without the outlier in CVH did not significantly alter findings. Both groups reported similar levels of positive wellbeing on the WEMWBS (CVH:  $M=45.57$ ,  $SD=12.23$ ; CNVH:  $M=44.54$ ,  $SD=9.59$ ).

**3.3.4 Hypothesis 4:** CVH report greater use of avoidant coping strategies compared to CNVH

Results found no significant difference between groups on avoidant coping styles, ( $MD=-.17$ ,  $p=.88$ ,  $d=-.05$ ). Ratings by CVH ( $M=6.96$ ,  $SD=3.83$ ) were similar to CNVH ( $M=7.13$ ,  $SD=3.69$ ). The highest subscale score for both groups was self-distraction ( $M \geq 3.4$ ), suggesting that among avoidant coping

strategies, carers preferred to distract themselves by watching TV/movies, working or doing other service substitute activities.

### **3.4 Overall functioning of carers**

In the overall sample, 30 of the 51 respondents (59%) scored at or above the cut-off (11) for clinically significant psychological distress on the CORE-10, and 32 of the 48 respondents (67%) scored below the mean score of 50.7 for positive wellbeing in the general population on the WEMWBS (Stewart-Brown & Janmohamed, 2008). Examination of mean scores confirmed that both carer groups scored within the mild anxiety range (5-9) of the GAD-7, and the mild depression range (5-9) of the PHQ-9. Inspection of individual scores indicated that 21 of the 48 respondents (44%) scored at or above the cut-off (8) for clinically significant anxiety on the GAD-7, and 17 of the 49 respondents (35%) scored at or above the clinical cut-off for depression (10) on the PHQ-9.

For the whole sample, the highest IPQ item-related score was found for 'timeline' (illness duration). Overall mean scores > 8.35 indicated strong carer beliefs the illness would last a very long time. The lowest item-scores were for 'personal control' ( $M < 4.2$ ), suggesting that carers believed that service users had limited control over their illness. In addition, 38 carers responded to the BIPQ open question on identifying what the main causes of the illness. Overall, the top two ranked factors were bereavement and childhood factors, while family/relationship issues and drug use tied for third rank. Causal factors are presented in rank order in Table 8.

*Table 8. Carer-reported causal factors of service user illness (in rank order)*

<i>Rank</i>	<i>Factors causing the illness</i>	<i>N (%)</i>
1	Bereavement	11 (29%)
2	Childhood factors (e.g. sexual abuse, bullying, upbringing)	9 (23.7%)
3	Family/ relationship difficulties	8 (21.1%)
3	Drug use (e.g. cannabis)	8 (21.1%)
4	Loneliness / isolation	7 (18.4%)
5	Personal difficulties (e.g. not achieving goals, poor communication, misunderstood)	6 (15.8%)
6	Work stress / conflicts	5 (13.2%)
6	Socio-economic issues (e.g. poverty, racism)	5 (13.2%)
6	Alcohol	5 (13.2%)
7	Bad company	4 (10.5%)
7	Genetics	4 (10.5%)
7	Stress	4 (10.5%)
7	Not doing much/not staying busy/ no interests	4 (10.5%)
8	'Trauma'	3 (7.9%)
8	Depression	3 (7.9%)
9	Chronic Illness / Disability, e.g. cerebral palsy	2 (5.3%)
9	Financial difficulties	2 (5.3%)
9	Domestic violence	2 (5.3%)
9	'Environmental factors' / 'circumstances'	2 (5.3%)
10	Homelessness	1 (2.6%)
10	War	1 (2.6%)
10	Spiritual problem	1 (2.6%)
10	Chemical imbalance in brain	1 (2.6%)
10	Menopause	1 (2.6%)
10	Empty-nest syndrome	1 (2.6%)
10	Low self-esteem	1 (2.6%)
10	Laziness	1 (2.6%)
10	Sleep deprivation	1 (2.6%)
10	Worrying	1 (2.6%)
10	Watching horror movies	1 (2.6%)

### 3.5 Summary of results

In summary, there were high levels of psychological distress and negative caregiving experiences reported by the sample. The highest ratings of carer distress in relation to service user presentation were associated with 'other

problems experienced by the service user' (i.e. problems other than the positive and negative symptoms of psychosis). The study did not find support for any of its four main hypotheses. Results indicated no significant hypothesised differences between the CVH and CNVH on caregiving appraisals, affective disturbance, avoidant coping and illness beliefs except for the 'IPQ-Identity' item, indicating that CVH perceived service users to have more severe symptoms of the illness. CNVH reported a greater need to back up service users.

## **4. Discussion**

Given the importance of supportive caregiving relationships in optimising patient outcomes in psychosis (Kuipers et al 2010; Reveier et al 2015) and the high prevalence of voice hearing in psychosis populations (Nayani & David, 1996), this study aimed to examine whether key caregiving appraisals and functioning differed between carers of service users who hear voices (CVH) and carers of service users who do not hear voices (CNVH). Given that voice hearing might present a more tangible and public sign of illness and potentially impact upon carer–service user communications, it was hypothesised that CVH would report more negative caregiving appraisals and negative illness beliefs, experience greater stigma and affective disturbance, and use less adaptive coping strategies.

### **4.1 Overall characteristics of carers: Comparison with previous literature**

The majority of carers who participated in the study were female and mostly the parents or partners of service users with psychosis, which is in keeping with other carer studies (e.g. Poon et al 2016; Kuipers et al., 2006). More than half of participants lived with their relative with psychosis, which is also consistent with the pattern of results recorded in previous studies (Addington

et al., 2003; Onwumere et al., 2008). About three quarters of the sample were from BAME backgrounds, representative of the large BAME populations in the targeted South London boroughs (Lambeth Council, 2014; Southwark Council, 2014).

High levels of psychological distress were reported by at least two thirds of the sample, and approximately 35-45% of participants reported clinical levels of depression and anxiety. These figures are comparable to results observed by other large population studies (Gupta et al., 2015; Poon et al., 2016) and smaller-scale studies of carers of adults with psychosis (Kuipers & Raune 2000; Dyck et al., 1999; Hayes et al., 2015).

Overall mean levels of avoidant coping appeared lower than levels reported in the literature (Onwumere et al., 2011, Raune et al., 2004). It is possible that carers in the present sample might have represented those who are less avoidant, by virtue of accessing support from dedicated carer services. It also seems plausible that participants might have adapted better to the service users' illness over time, especially given the long-term nature of difficulties faced by service users in the targeted teams, compared to first episode services (Onwumere et al., 2008, 2011; Parabiaghi et al., 2007), and the average age of the carer sample. This is consistent with research suggesting that carers tend to develop more active coping strategies with age and at later phases of service users' illness (Kartalova-O'Doherty & Doherty, 2008). The broader literature on the evolution of carer coping over time suggests a dynamic process of trial and error approaches through which carers attempt to find the most effective strategies to cope with their relative's illness and the impact it has on their own lives (Onwumere et al., 2016; Rose et al. 2002).

In addition, overall levels of stigma also seemed lower compared to the high levels of stigma reported by carers in psychosis in other studies (e.g. Corrigan & Miller, 2004; González-Torres et al., 2006; Veltman et al., 2002). The ECI stigma subscale has a maximum score of 25, and mean ratings in the current study were less than 8. A recent Swedish study suggests that carers in

psychosis may not experience high levels of stigma themselves, even when their ill relatives are stigmatised (Allerby et al., 2015). They suggest that increased efforts to raise awareness among service providers about stigma and its effects might mitigate the impact of stigma traditionally associated with the caregiving role in psychosis.

Two thirds of the sample reported positive wellbeing scores below the general population norm (Stewart-Brown & Janmohamed, 2008). This is perhaps unsurprising given the higher levels of distress and affective disturbance previously reported. These findings warrant interest on their own, but are particularly important considering participants were a group fulfilling important caregiving roles for unwell relatives. This further highlights the importance of identifying carers' needs and the factors that impact negatively on their wellbeing. Furthermore, in line with Lazarus and Folkman model of stress-appraisal-coping (1984), which links psychological well-being with appraisals of circumstances rather than objective reality, further research is needed to investigate the relationship between positive wellbeing and appraisals of caregiving.

Another important aspect of carers' appraisals are their beliefs about the service user's illness (Kuipers et al., 2010). Negative illness representations are associated with increased carer distress, (Addington et al., 2003; Barrowclough et al., 2014). Carers in the present study held many threatening beliefs about psychosis, providing the highest ratings around the 'timeline' item (long illness duration) of the B-IPQ. This might be considered unsurprising and reflect their subjective experience of providing care over a long period, as service users in the 'Promoting Recovery' service pathway tend to have long illness histories and contact with mental health services. Carers provided the lowest ratings for the 'personal control' item, indicating their belief that service users had little control over the illness. This may reflect carers' impressions – gathered while caring closely for their relative – that the illness and related experiences are not directly within the relative's control. It is possible however, that it also reflects a sense of hopelessness and pessimism about the future.



Another important aspect of illness belief concerns causal attributions made by the carer (e.g. Barrowclough et al., 1995). In the present study, carers' perceptions of illness causation varied widely. Overall, a considerable number of carers provided causal attributions that were external to the service user, such as bereavement, difficult childhood experiences, family/relationship difficulties, trauma and socio-economic issues such as poverty and racism. Prevalent casual attributions internal to the service user included taking drugs, keeping bad company, being highly stressed, drinking alcohol and experiencing personal difficulties, especially around not achieving goals. Thus consistent with the wider literature (Barrowclough & Hooley, 2003), carer attributions of causation were mixed, comprising causes that were linked directly to patient behaviours (e.g. substance use) and those that were less so (e.g. spiritual problem).

## **4.2 Impact of voices on carers in psychosis**

There is a remarkable paucity of research into the impact of specific symptoms in psychosis on carers (Onwumere et al. 2016). The Carer Experience of Symptoms-Questionnaire allowed for the exploration of carer distress associated with individual symptom categories of delusions, auditory hallucinations, low mood, low motivation and poor self-care. The current study extends the literature on the 'symptom-orientated approach' in psychosis by investigating carer experience in relation to discrete service user symptoms. Significant levels of carer distress were associated with service user symptoms such as voices, delusions, low motivation and low mood. However, the highest carer distress was related to service user problems other than the positive and negative symptoms of psychosis. Moreover, three times as many CVH compared to CNVH reported that service users experienced delusions. This is in keeping with evidence that hallucinations and delusions in psychosis are strongly associated with each other (Krabbendam et al., 2004; Van Os et al., 2000). CVH also appeared more distressed by delusions than CNVH. It is possible that auditory verbal hallucinations (AVH) may give rise to or exacerbate delusional interpretations (e.g. Chadwick & Birchwood, 1994), thus increasing clinical severity. It could be argued that delusional explanations

about the voice hearing experience may be the area most associated with the carer distress particularly if carers were implicated in the explanations. Recent data suggests that carers can experience distress and difficulties when they are included in their relative's delusional explanations (Onwumere et al. 2016).

To the authors' knowledge, this is the first study to date to explore the pathways by which AVH may interact with carer wellbeing and the caregiving relationship. However, the main hypotheses were largely unsupported. Thus, against predictions, the results failed to identify significant differences between the carer groups in their negative caregiving appraisals, stigma, affective disturbance and coping. The findings are partially consistent with a UK study by Harvey et al. (2001) which examined whether the caregiving appraisals of 154 relatives of patients with severe psychotic illness were influenced by patient symptomatology. They found that caregiving appraisals were not predicted by patients' symptomatology, but by other factors such as patient age, employment status, length of illness and level of social functioning.

One possible explanation for results in the present study is that CVH did not find AVH the most distressing aspect of service users' current illness presentation. Ratings by CVH on the CES-Q showed roughly equivalent ratings of distress in relation to service users' voices, delusions, low mood and motivation, suggesting that CVH experienced all these symptoms as equally distressing. If voices were not the primary distressing concern of CVH, this might have influenced the non-significant findings between the groups on the target carer variables. This would be an important consideration for future studies. In addition, results indicating that the negative symptoms of psychosis were just as distressing as the positive symptoms for CVH are consistent with the symptom-focused literature suggesting that carers might be as affected by the negative symptoms and functional impairments associated with psychosis, as the positive symptoms (Addington et al., 2003; Roick et al., 2006). It might be argued that the depressive symptoms, although less disruptive and more covert, are equally problematic and demanding of carer resources, including their time and emotional and practical support. They are also more persistent than positive psychotic symptoms which are often episodic, precipitate a crisis

and receive prompt intervention (Dyck et al., 1999; Tucker et al., 1998). In the community, low mood and motivation difficulties in service users may therefore receive less attention and remain harder to intervene with. In turn, this may leave some carers feeling unsupported in dealing with the behavioural and functional consequences of low mood and motivational difficulties.

Interestingly, carers in both groups gave the highest distress ratings for 'other problems' faced by service users in addition to psychosis. This is consistent with findings by Hjärthag et al. (2010) indicating that the overall functioning of patients had the single biggest impact on carer burden, even more than symptom severity. This finding suggests that carers in the present study perceived psychosis as one being one among several significant difficulties faced by service users, which might explain the non-significant findings between the groups. In keeping with literature suggesting that individuals with psychosis commonly experience co-morbidities and social functioning difficulties (Achim et al., 2011; Bellack et al., 2007; Buckley et al., 2009; Green et al., 2004, 2008), this finding underscores the need for targeted interventions to address the psychosocial functioning of service users in order to alleviate associated carer burden (Moller-Leimkuhler & Wiesheu, 2012).

It should be noted that the study recorded two significant differences between CVH and CNVH. Firstly, in line with hypotheses, results on the B-IPQ suggested that CVH held a significantly greater belief that service users experienced more severe symptoms of their illness compared to CNVH. As mentioned earlier, CVH were three times as likely to also report that their relatives experienced delusional beliefs, which is likely to have been reflected in their scores and negative appraisals about the illness.

An unexpected second finding was that CVH reported a significantly lower need to step in and respond to unmet needs in their relatives compared to CNVH. It might be argued that service users with more complex illness presentations involving AVH receive greater service input and consequently have lower levels of unmet needs that carers have to address and provide

informal 'back up' for. In keeping with research suggesting that a negative appraisal of caregiving is associated with the number of patient needs met by the carer (Tucker et al., 1998) and patients' support by a Community Psychiatric Nurse (Joyce, Leese & Szmukler, 2000), CNVH might perceive greater demands of caregiving that arise from having to supplement significant areas of unmet need for service users with less obviously severe presentations. However, as no corrections for multiple-testing were undertaken, it is possible that these may be chance findings.

### **4.3 Strengths of the study**

The present study had some notable strengths. Firstly, black and ethnic minority (BAME) carers were well represented in the present sample, which reflects the local service population. This differed notably from the ethnic composition of carer samples reported in the South London borough of Southwark, where carers from black ethnic backgrounds have been underrepresented in recruited samples (Szmukler, Kuipers et al., 2003). It is possible that also recruiting from Lambeth might have contributed to a more representative sample. A related strength was the recruitment of carers via well-established carer support services that were already integrated within community mental health teams. This rendered it easier to access a wide range of carers, since the carer support service engages with anyone who supports service users in any way regardless of whether they consider themselves to be a carer or not (Allen et al., in press).

Secondly, variables studied were based on theoretically informed sources of distress in carers such as negative caregiving appraisals and illness beliefs, stigma and avoidant coping styles, which have been highlighted by seminal models of caregiving in psychosis (e.g. Kuipers et al., 2010). In addition, the present study also focused on positive wellbeing, overcoming a notable criticism that the caregiving literature has tended to focus on the distress and burden which accompanies the role (Onwumere, Smith & Kuipers, 2010, p.107; Szmukler, 1996).

Finally, the assessment process also presented certain strengths. The measurement protocol employed validated and reliable measures which have been widely used to study carers in psychosis, and therefore lent themselves to comparison with other groups of carers. Another strength was that assessments were carried out face-to-face with carers. This allowed opportunities for assisting carers in completing the measures, clarifying items which carers found confusing and for carers to elaborate on their responses if needed.

#### **4.4 Study limitations**

The study presented limitations in five main areas. Firstly, it employed a cross sectional design which precludes conclusions being drawn about causation, leading to findings for which there may be several plausible explanations. In addition, a cross sectional study design only assess the variables of interest at one point in time. However in reality, factors of interest may fluctuate over time and the caregiving relationship may therefore change such that a longitudinal study may find effects over time, which may not be apparent cross-sectionally.

Secondly, while the sample heterogeneity and reflection of the local population is a strength, the predominance of maternal carers, and the lack of representation of other carer groups such as siblings and adult offspring might impact on the generalisability of findings. Moreover, as carers were recruited via dedicated carer services, there may have been a selection bias in favour of more help-seeking carers who opted in to access support for the difficulties experienced in their caregiving roles. The selective nature of the sample may have influenced findings regarding the levels of affective disturbance, avoidant coping and stigma observed, whereby carers who were more or less impacted by their role engaged with the service.

The next limitation relates to the measurement protocol which was intentionally designed to access and collect information from carers only. However, collecting illness-related information from service users may have offered useful markers of their illness severity. Studies indicate that caregiving appraisals can be mediated by length of service users' illness, levels of disability and social functioning (Harvey et al., 2001; Joyce et al., 2000; Onwumere et al., 2008). Moreover, the study did not assess additional factors which might have accounted for the clinical levels of stress and anxiety seen in the sample. This is important given that carers take on the responsibilities of informal caregiving in addition to their existing roles (Onwumere et al., 2008). Hence their affective disturbance, caregiving appraisals, illness beliefs and coping strategies may have been impacted by factors unrelated to the service user (e.g. carer unemployment, financial and housing problems, caring for other family members). Additionally, the CES-Q was a new screening measure developed specifically in the context of the new carer support services and remains to be validated with wider carer populations. CVH and CNVH were identified based on their response to the CES-Q item relating to hallucinations in the service user. While most carers provided decisive 'yes' or 'no' answers on this item, a few carers indicated, in discussion with the researcher, that they were unsure whether or not their relative heard voices, and reflected on their response before committing themselves to an answer. Thus it is possible that some carer reports of auditory hallucinations, and therefore current groupings, may not have been accurate. However, the function of the CES-Q is to evaluate the carer's *appraisal* of service user difficulties, which is in keeping with the aims of the present study.

A final limitation was the missing data due to incomplete measures, which increased potential for non-response bias. A closer examination of non-responders showed that double the number of non-responders were CVH compared to CNVH. Non-completion could be taken as a proxy measure of distress and burden, but further research is needed to confirm this. No correction was made for multiple testing, so the two significant group differences reported must be viewed with caution. The sample size was small

and the study was powered only to detect large effects. However, lack of power to detect smaller effects did not appear to be the key factor in the failure to find significant between-group differences: differences between groups were very small, and often in the opposite direction to that hypothesized.

## **4.5 Future research**

Further research is needed to investigate how specific service user symptoms impact upon carers in psychosis. Studies using larger, more representative samples would facilitate a systematic investigation of the differences in carer variables based on the predominant problems faced by service users. It would be interesting for future research to study carers who have not engaged with carer-support services, and carers of service users in various stages of the illness, such as first-episode psychosis. The present study provides effect sizes which can be utilised for power calculations in future studies. Qualitative research using focus groups could also supplement findings about what aspects of the service user's illness impact significantly on their functioning and caregiving responsibilities.

A review by Awad and Voruganti (2008) stressed the need for further research into understanding the role of ethnicity on caring for service users with different symptoms, particularly in Western societies that are increasingly multi-cultural and multi-ethnic. Studies have shown that African Americans feel less burdened by and hold fewer rejecting attitudes towards relatives with schizophrenia compared to White Americans (Horowitz & Reinhard, 1995; Guarnaccia et al., 1996). However, African samples also appear more distressed (Ukpong, 2006) and less tolerant of psychotic behaviour than other ethnicities (Tessler et al., 1990). The present study had a much higher proportion of BAME carers than previous UK studies but was not adequately powered to detect differences between the small ethnic groups within CVH and CNVH groups. Further research is indicated to better explore differences in the experiences of carers from BAME backgrounds (Boydell et al., 2014).

## 4.6 Clinical implications

Although preliminary, the two significant differences found between CVH and CNVH, may have clinical implications for carer interventions. Firstly, CVH reported that service users experienced more severe symptoms of the illness. Thus an important consideration when planning interventions for CVH may be the provision of psychoeducation, especially focusing on the interplay between AVH and other symptoms (e.g. delusions). Secondly, CNVH perceived a greater need to back up service users. It is possible that carers of service users with less obvious positive symptoms might require more support than they currently receive from services – which tend to focus on the remission of positive symptoms.

However, it is also important to note that the study showed that overall, carers reported clinically significant levels of psychological distress, anxiety and depression and were most distressed by service user problems other than those relating directly to psychosis. These findings have important implications for both assessment and intervention with carers. Firstly, services need to prioritise the assessment of carers' psychological morbidities, as well as their specific concerns regarding the service user, and the additional problems service users face (other than psychosis) which impact on carers' functioning and experiences of caregiving. Carer interventions should be based on such detailed assessments of carer needs (Barrowclough et al., 1999; Sellwood et al., 2001) rather than specific service user symptoms. This is in keeping with recent updated NICE guidelines (2014) which propose that all carers have a statutory right to a formal carer's assessment provided by social care services, and recommend that carers' needs should be assessed by mental health services and used to inform individualised care plans for carers (UK NICE, 2014). Preliminary evidence citing carer gains following brief needs-based psychological interventions (Roddy et al., 2014) suggests that carers value and derive important benefits from such support.

The study also found that overall, carers perceived the illness to have a long course, and service users to have very limited personal control over the illness.



Such negative illness beliefs can be a useful target of carer interventions. Providing psychoeducation about recovery and using techniques to bolster hope, may help carers arrive at a more realistic understanding of prognosis (Glynn et al., 2006) and cope better with the strains of caregiving in long-term psychosis.

## **4.7 Conclusion**

In summary, this study suggests carers of voice hearers perceived service users to have more severe symptoms compared to carers of service users who do not hear voices. CNVH, on the other hand, perceived a greater need to supplement the care and input they received from services. There were no other significant differences between CVH and CNVH, in terms of their caregiving appraisals, stigma, affective disturbance and avoidant coping. Thus, in the framework of the cognitive model of caregiving, the number of differences between the groups proved to be very small.

Overall, carers reported clinically significant levels of affective disturbance. Negative caregiving appraisals and illness beliefs were comparable to other studies, and indicated that the most negative appraisals centred on service users' difficult behaviours, and duration of illness. However, carers reported low levels of stigma and avoidant coping. There is a need for further studies of these groups accounting for issues such as pre-existing mental health difficulties in carers, measurement of EE and cross-cultural variability. The predictive value of such studies can be enhanced through repeated measurement. This study provides further evidence that the caregiving role in psychosis is stressful and presents challenges beyond the direct symptoms of psychosis. Efforts to augment support to carers are critical, and interventions offered should be independent of voice-hearing presentation and be based on comprehensive assessment of carer needs.

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## 6. Appendices

### APPENDIX 1: Confirmation of Ethical Approval



Telephone: 020 7972 2582

06 July 2015

Dr. Suzanne Jolley  
Research and Hon. Consultant Clinical Psychologist  
King's College London  
PO Box 77, Department of Psychology  
Institute of Psychiatry, Psychology and Neuroscience  
London SE5 8AF

Dear Dr. Jolley

<b>Study title:</b>	<b>Evaluating outcomes and change processes in cognitive behavioural interventions for caregivers of people with psychosis.</b>
<b>REC reference:</b>	<b>15/LO/0680</b>
<b>IRAS project ID:</b>	<b>166679</b>

Thank you for your letter of 30 May 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Stephanie Hill, [nrescommittee.london-londonbridge@nhs.net](mailto:nrescommittee.london-londonbridge@nhs.net). Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

#### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

#### Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the

A Research Ethics Committee established by the Health Research Authority

study.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations*

#### Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact [hra.studyregistration@nhs.net](mailto:hra.studyregistration@nhs.net). The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

#### **Ethical review of research sites**

##### **NHS sites**



The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

#### Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Covering letter on headed paper [Cover letter to REC]	v2	24 March 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Indemnity for sponsor]	N/A	14 July 2014
GP/consultant information sheets or letters [Letter to GP v1 281214]	v1	28 December 2014
Non-validated questionnaire [Experience of symptoms v1 161214]	v1	16 December 2014
Non-validated questionnaire [FFQ personal goals v1 161214]	v1	16 December 2014
Non-validated questionnaire [Feedback form v1 161214]	v1	16 December 2014
Other [EMH Supervisor CV]	N/A	23 February 2015
Other [EOD Supervisor CV]	N/A	24 February 2015
Other [PK Student CV]	N/A	25 February 2015
Other [Carer Crisis Plan v1 161214]	v1	16 December 2014
Other [Carer demographics v1 161214]	v1	16 December 2014
Other [Team contact information v1 161214]	v1	16 December 2014
Participant consent form [Consent form v1 281214]	v1	28 December 2014
Participant information sheet (PIS) [Carers]	2	30 May 2015
REC Application Form [REC_Form_27032015]		27 March 2015
Referee's report or other scientific critique report [Peer review 040215]	v1	04 February 2015
Referee's report or other scientific critique report [BUTLER APPROVAL v1 050914]	v1	05 September 2014
Referee's report or other scientific critique report [KOCHOPSARAMPIL APPROVAL 071014]	v1	07 October 2014
Research protocol or project proposal [Protocol Evaluating Interventions for Caregivers of People with Psychosis v2 220215.doc]	v2	22 February 2015
Response to Request for Further Information		30 May 2015
Summary CV for Chief Investigator (CI) [CV for CI]	N/A	23 February 2015
Summary CV for student [LB Student CV]	N/A	24 February 2015
Summary CV for supervisor (student research) [JO Supervisor CV]	N/A	25 February 2015
Validated questionnaire [Five minute speech sample]	N/A	
Validated questionnaire [Acceptance & Action Questionnaire v1 161214]	v1	16 December 2014
Validated questionnaire [Caregiver Activity survey v1 161214]	v1	16 December 2014
Validated questionnaire [Caregiver Guilt Questionnaire v1 161214]	v1	16 December 2014
Validated questionnaire [Compassion to others scale v1 161214]	v1	16 December 2014
Validated questionnaire [COPE v1 161214]	v1	16 December 2014
Validated questionnaire [CORE-6 v1 161214]	v1	16 December 2014

Validated questionnaire [CORE-10 v1 ]	v1	16 December 2014
Validated questionnaire [ECI (F) v1 161214]	v1	16 December 2014
Validated questionnaire [ECI (M) v1 161214]	v1	16 December 2014
Validated questionnaire [Five facet mindfulness v1 161214]	v1	16 December 2014
Validated questionnaire [GAD7 v1 161214]	v1	16 December 2014
Validated questionnaire [IPQ (F) v1 161214]	v1	16 December 2014
Validated questionnaire [IPQ (M) v1 161214]	v1	16 December 2014
Validated questionnaire [PHQ9 v1 161214]	v1	16 December 2014
Validated questionnaire [Short Compassion for self scale v1 161214]	v1	16 December 2014
Validated questionnaire [WEMWBS v1 161214]	v1	16 December 2014
Validated questionnaire [Timebudget v1 161214]	v1	16 December 2014

### Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

### After ethical review

#### Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

### User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

### HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at <http://www.hra.nhs.uk/hra-training/>

With the Committee's best wishes for the success of this project.

Yours sincerely

A handwritten signature in black ink, appearing to read 'D. Bartlett', with a small 'pp' or similar mark to the left.

**Professor David Bartlett**  
Chair

Email: [nrescommittee.london-londonbridge@nhs.net](mailto:nrescommittee.london-londonbridge@nhs.net)

Enclosures: "After ethical review – guidance for  
researchers" (SL-AR2)

Copy to: Mr Keith Brennan  
Jenny Liebscher, South London & Maudsley NHS Foundation Trust

Dr. Suzanne Jolley  
Research and Hon. Consultant Clinical Psychologist  
King's College London  
PO Box 77, Department of Psychology  
Institute of Psychiatry, Psychology and Neuroscience  
London SE5 8AF

5<sup>th</sup> October 2015

Dear Dr Jolley,

**Trust Approval: R&D2015/083**

**Title: Evaluating outcomes and change processes in cognitive behavioural interventions for caregivers of people with psychosis**

**REC Reference: 15/LO/0680**

I am writing to confirm approval for the above research project at South London and Maudsley NHS Foundation Trust. This approval relates to work in the Psychosis CAG and to the specific protocol and informed consent procedures described in your R&D Form. Any deviation from this document will be deemed to invalidate this approval. Your approval number has been quoted above and should be used at all times when contacting this office about this project.

Amendments, including extending to other Trust directorates will require further approval from this Trust and where appropriate the relevant Research Ethics Committee. Amendments should be submitted to this R&D Office by completion of an R&D Amendment form together with any supporting documents. A copy of this is attached (*R and D Amendment Form V3.doc*), but is also available on the R&D Office website.

[King's College London - Research and development approval](#)

I note that King's College London/South London and Maudsley NHS Foundation Trust and Canterbury Christ Church University will be taking on the role of Sponsor for this study.

Approval is provided on the basis that you agree to adhere to the Department of Health's Research Governance requirements including:

- Ethical approval must be in place prior to the commencement of this project.
- As Chief Investigator and/or Principal Investigator for this study you have familiarised yourself with, and accept the responsibilities commensurate with this position, as outlined in the Research Governance Framework

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_4122427.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4122427.pdf)



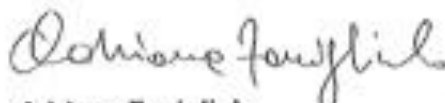
- Compliance with all policies and procedures of the Trust which relate to research, and with all relevant requirements of the Research Governance Framework. In particular the Trust Confidentiality Policy.  
<http://www.slam.nhs.uk/media/107386/confidentiality%20policy.pdf>
- Where the study is a clinical trial/interventional study and as such affects a patient's clinical care, it is a Trust requirement to ensure that the patient's participation in the study is noted in the patient's health record, and include a copy of the patient's consent form in the record. This is to ensure that information about patients' involvement in clinical trials can be accessed at a later date, for example in the event of a serious incident investigation.
- Co-operating with the Trust R&D Office's regular monitoring and auditing of all approved research projects as required by the research governance framework, including complying with ad hoc requests for information.
- Informing the Trust's Health and Safety Coordinators and/or the Complaints Department or of any adverse events or complaints, from participants recruited from within this Trust, which occurs in relation to this study in line with Trust policies. Contact details are available from the R&D Office if required.
- Sending a copy of any reports or publications which result from this study to the Trust Departments involved in the study if requested.
- Honorary Contracts must be in place prior to patient contact for all relevant members of the research team. Advice on this will be provided by the R&D Office at the point of obtaining R&D approval and on an ongoing basis for new members of staff joining the research team.
- Sending a copy of the annual reports and end of project notification submitted to ethics.

Failure to abide by the above requirements may result in the withdrawal of the Trust's approval for this research.

If you wish to discuss any aspect of this research approval with the R&D Office, please contact Jenny Liebscher [jennifer.liebscher@kcl.ac.uk](mailto:jennifer.liebscher@kcl.ac.uk) in the first instance.

I wish you every success with this study.

Yours sincerely



**Adriana Fanigliulo**  
Research Governance Facilitator  
SLaM/IoPPN R&D Office

Enc. R&D Approval Amendment Form

## APPENDIX 2: Information Sheet and Consent Form



Institute of  
Psychiatry,  
Psychology &  
Neuroscience

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### Information Sheet Version 1 – 28/12/14

#### Evaluating Interventions for Caregivers

We are inviting you to take part in a research project.

You should only take part if you want to.

If you do not want to take part, this will not affect the usual care or services that you, or the person you care for, receive in any way. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully.

One of our team will go through the information sheet with you and answer any questions you have. This should take about 15 minutes.

Talk to other people about the project if you want to.

- Part 1 tells you the purpose of this project and what will happen to you if you take part.
- Part 2 gives you more detailed information about how the project will be carried out.

Please ask us if there is anything that is not clear or if you would like more information.

**Contact details: Lucy Butler & Priya Kochuparampil, SHARP team, 308-312 Brixton Road, SW9 6AA. 0207 848 5028**

*REC Reference Number: 15/LO/0680*

**You will be given a copy of this information sheet.**

## Part 1

**What is the purpose of the project?** We want to find out how things change for carers of people in promoting recovery services while they are receiving support from a carer support service. We also want to find out more about the kind of difficulties caregivers have, and what help they might need to deal with them.

**Why have I been asked to take part?** We will ask all caregivers in the services, who are feeling well enough to participate, if they would like to take part.

**What will I be asked to do?** If you would like to take part in the study, you will first need to sign the form at the end of this sheet, to say that you are happy to go ahead.

There are three ways to take part:

**a) firstly**, you can agree for us to use the questionnaires you have already completed routinely in the service (usually when we first meet you, and after three months, when you have completed an 'intervention' (a group or individual course of support)) for this research project. You will not need to do anything else.

**b) secondly**, you can agree to up to two extra meetings with a researcher to complete the same questionnaires again, before and after any additional interventions you complete, specifically for this research project. We would ask you to complete the measures again before an intervention (the first extra meeting), if you last completed them more than three months ago. We would ask you to complete the measures again after an intervention (the second extra meeting) if you are going on to complete an additional intervention. We will not ask you to attend any more than two extra meetings as part of the research, and we would expect each meeting to last about an hour. We will try to arrange these meetings at times when you are attending the service anyway. We will also offer you £5 for each extra meeting towards your time and travel. The purpose of the extra meetings and questionnaires is to find out more about how things change, and when, for carers in different circumstances, after different interventions.

**c) thirdly**, you can agree to complete a short (5 minute), audio-recorded interview about your relationship with the person you are caring for. We would ask you to complete this twice, once before and once after an intervention, at the same time as you complete the other questionnaires, so we would not expect you to need to make an extra visit. The interview would be specifically for the research project. There is more information about the interview at the end of this information sheet (Appendix 1).

**Will my taking part in the study be kept confidential?** We work closely with the carer support team and the clinical team for the person you are caring for, and the information you give us will usually be shared with these services as it may help them to provide support for you and care for the person you are caring for. The researcher will note this down on the electronic notes system, where they will also note that you are taking part in the study and when they meet with you. If you tell us anything about someone being hurt or not safe, we will have to tell other people who are there to help with these kinds of situations. More details are included in Part 2.

**How will the information I give you be kept?** All the answers you give to the questionnaires will be kept on paper and as an electronic file. They will only be identifiable by a number. If you complete the audio-recorded interview, we will transcribe this (i.e. write it down, word for word), and keep a paper and electronic copy, from which we will remove personal details like names. Like the questionnaires, this will be identifiable by a number. We will not keep the audio-recording, once we have transcribed it. Your name will be kept separately, with the number, on paper, so that we can identify your questionnaires in the future if we need to (for example, if you decide you no longer want to be part of the study). We will only identify your questionnaires for a reason like this. Your details will be kept for up to 10 years, and then will be confidentially destroyed. We will keep a completely anonymous copy of the electronic file indefinitely, from which you will not be able to be identified at all. At the very end of the study, you will be able to have a summary of the results, if you would like.

**Is there any risk from taking part?** We do not think that this study will be harmful in any way. We want it to be helpful and the questionnaires have all been designed for caregivers in particular, or adults in the general population, and have been approved by researchers who have many years' experience of working in this field. However if you feel distressed in any way by taking part, please talk to the researcher, or to one of the carer support workers, who will be able to help you.

**Are there any benefits of taking part?** There is no direct benefit to you from taking part in the study. We hope to find out more about how the difficulties facing carers impact on their day to day lives, so we can provide the most effective support in the future. People also sometimes find completing the questionnaires interesting and helpful.

**Do I have to take part?**

It is up to you to decide whether or not to take part in this study. If you decide to take part, you are still free to stop at any time and without giving any reasons. This will not affect any other help or support that you, or the person you care for, will be offered.

**What happens when the project stops?**

We will ask if you would be willing to be contacted regarding future projects, and if you would, we will keep your name and contact details. You will be able to ask us not to contact you at any time, and this will not affect you, or the person you are caring for, in any other way.

**This completes Part 1 of the Information Sheet.**

**If the information in Part 1 has interested you and you are thinking about taking part, please continue to read the additional information in Part 2 before making any decision.**

## **Part 2: What if there is a problem?**

**What if relevant new information becomes available?** Sometimes we get new information during a project. If we find out anything new about any of the questionnaires which means it might be harmful or upsetting for you in any way, we will tell you at once and you can decide whether or not you want to carry on.

**What will happen if I no longer want to carry on with the study?** If you decide you no longer want to take part, you should let us know at once. A member of the research team will talk to you about which parts you no longer want to be involved in (for example, you might not want to do extra questionnaires, but feel OK with us using the questionnaires you have already completed). We would like to still keep the information you have already given us if this is possible, but we will check this with you as well. You can tell us that you would like us not to keep any information at all, and in this case we will destroy all our copies of the information you have given us. This will not affect any other support you might be offered, or your rights in any other way. The only exception to this will be information that is important for your own wellbeing, or the wellbeing of the person you are caring for, care, or that relates to any risk of somebody being hurt or unsafe. We will sometimes have to hand this information over to the clinical team, and will be unable to destroy it because of its importance.

**Complaints:** If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions, or to the staff on the ward. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure – Contact Patient Advice and Liaison Service (PALS) on: 0800 731 2864 or [pals@slam.nhs.uk](mailto:pals@slam.nhs.uk).

**Harm:** In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation against your local NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**Will my taking part in this study be kept confidential?** All information which is collected about you during the course of the research will be kept strictly confidential. All the answers to the questionnaires will be kept on paper and on an electronic database. They will be kept securely and anonymously and will be identifiable only by a number, not by name. Your name will be kept separately, with the number, on a different database and on paper, so that we can identify the questionnaires and recordings in the future if we need to (for example, if you decide you no longer want to be part of the study). We will only identify your questionnaires for a reason like this. Paper copies of questionnaires will be kept securely by the researchers in a locked filing cabinet in a locked office. Your details will be kept for up to 10 years, and then

will be confidentially destroyed. We will keep a completely anonymised copy of the database indefinitely, from which you will not be able to be identified at all.

The information you give will usually be available only to the research team, the carer support team and the clinical team for the person you care for. Information that you provide on the assessment measures, interviews and any support and interventions will not usually be shared with the person you provide care for. We work closely with the clinical services and the information you give us will usually be shared with the clinical team if it will help them to support you and to provide care for the person you care for. The researcher will note this down on the team's notes system, where they will also note that you are taking part in the study and when they meet with you. In addition, should you give any information, such as criminal disclosures, or information relating to anybody's safety, which requires action, we are legally obliged to act on this information, and to pass this information on to others, including services who are able to deal with these concerns, which may include Social Services or the Police.

**What will happen to the results of the research study?** We intend to publish the results of the research. You will not be personally identified in any report/publication. We sometimes use quotes from participants when we write about the research. In this case we will tell you what we want to write and where it will be seen and check that you agree.

**Who is organising and funding the research?** The research is organised by the team, who are members of academic and clinical staff at the Institute of Psychiatry, Psychology and Neuroscience, King's College London and the South London & Maudsley NHS Foundation Trust.

**Who has reviewed the study?** The study has been reviewed by the London-London Bridge Research Ethics Committee, of the National Research Ethics Service (reference number 15/LO/0680) and by the Joint Institute of Psychiatry, Psychology & Neuroscience/South London & Maudsley NHS Foundation Trust Research & Development Office.

**How can I take part?** If you would like to take part in this project, please complete the attached consent form. If you have any questions or concerns about taking part in this study please contact the researchers below.

**Contact Details: Lucy Butler & Priya Kochuparampil, SHARP team, 308-312 Brixton Road, SW9 6AA. 0207 848 5028**

## **Appendix 1: More details about the audio-recorded interview**

If you agree to complete the five minute research interview, we will introduce this in a standard way. We will say to you:

“I’d like to hear your thoughts about [the person you care for] in your own words and without my interrupting you with any questions or comments. When I ask you to begin, I’d like you to speak for 5 minutes, telling me what kind of a person [the person you care for] is and how the two of you get along together. After you have begun to speak, I prefer not to answer any questions. Are there any questions you would like to ask me before we begin?”

We won’t interrupt you or ask you anything during the five minutes, but we might prompt you if you run out of things to say, by saying something like ‘please carry on’. You will be able to stop the interview at any time, or change your mind about taking part, without giving us a reason, and without it affecting your involvement with the service in any way.

We will transcribe the audio-recording (write it down, word for word), taking out any names or other personally identifiable information. We will keep paper and electronic copies of the transcript without your name, identifiable by a number, in the same way as the rest of the study information (see Parts 1 and 2 above).



Institute of  
Psychiatry,  
Psychology &  
Neuroscience

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**CONSENT FORM V1 28/12/14**

*Title of project: Evaluating Interventions for Caregivers*

Names of researchers: *Lucy Butler, Priya Kochuparampil*  
*Please initial boxes:*

1. I have read the information sheet dated 28/12/2014 for the above project, and one of the researchers has talked to me about it. I have had enough time to think about it and ask questions.
2. I understand that taking part is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.
3. I am willing for the researcher to let my GP know that I am taking part in the study.
4. I am willing for the researcher to contact other professionals with any information relevant to my care, or the care of the person I care for, should this become apparent while we are taking part in the study.
5. I am willing for the researchers to pass this information on to the carer support team to be recorded in the carer section of the clinical team's electronic notes for the person I care for.
6. I give permission for information from the carer sections of the medical notes for the person I care for to be passed on to the researchers by the carer support team, if it is relevant to taking part in this research (for example, to get an address, age or confirm clinical information).
7. I am willing for the research interview to be audio-recorded.
8. I understand that information relating to me taking part in this study will be stored in an electronic file for up to 10 years.
9. I agree to take part in the above study.
  - a) using questionnaires I have already completed within the carer support service.
  - b) completing the questionnaires at extra time points and the research interview

\_\_\_\_\_  
Name of participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

10. I have explained the study to this participant and answered their questions honestly and fully.

\_\_\_\_\_  
Name of researcher

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

## APPENDIX 3: Copies of Measures used in the Study

### Measures Pack

1. ***Demographic questions***
2. ***Experience of symptoms***
3. ***Caregiving:*** Experience of Caregiving Inventory
4. ***Illness beliefs:*** Brief Illness Perception Questionnaire
5. ***General distress:*** CORE-10
6. ***Depression:*** PHQ-9
7. ***Anxiety:*** GAD-7
8. ***Wellbeing:*** The Warwick-Edinburgh Mental Well-being Scale
9. ***Coping:*** Brief COPE Inventory

## DEMOGRAPHICS QUESTIONS

<b>Name</b>	
<b>Age</b>	
<b>Ethnicity</b>	
<b>Email address</b>	
<b>Marital status</b>	
<b>Employment status</b>	
<b>Relation to care recipient</b>	
<b>GP</b>	

<b>Are you living with the person you care for?</b>	
<b>How many hours of weekly contact do you have with the person you care for:</b>	
<b>Do you provide care for anyone else? If yes, specify who.</b>	
<b>In general, do you feel that you have someone that you can confide in? If yes, specify who.</b>	
Yes	No

<b>During the past month, how often have you had difficulties getting to sleep?</b>	
1= not during the past month 3= once a month 5= everyday	2= once a week 4= most days
<b>During the past month, how would you rate your sleep quality?</b>	
1=very poor 4=good	2=poor 5= very good
3= no problems	

<b>In the last 12 months has the relative you care for been verbally aggressive towards you?</b>		
1 = <i>never</i>	2 = <i>once</i>	3 = <i>occasionally</i>
4 = <i>more than once a week</i>	5 = <i>all the time</i>	
<b>In the last 12 months has the relative you care for been physically aggressive towards you?</b>		
1 = <i>never</i>	2 = <i>once</i>	3 = <i>occasionally</i>
4 = <i>more than once a week</i>	5 = <i>all the time</i>	

<b>Are you currently using services in South London and Maudsley (SLaM) NHS Trust?</b>	
Yes	No

## Carer Experience of Symptoms-Questionnaire (CES-Q)

*To support us with being able to understand your experiences and identify the areas we could best support you with, we would be grateful if you could spend a few minutes answering the following questions.*

<b>1a. In your opinion, does your relative have difficulties with maintaining their self-care?</b>											
Yes						No					
<b>1b. To what extent, does this upset you?</b>											
0	1	2	3	4	5	6	7	8	9	10	
Not at all upset						Extremely upset					
<b>2a. In your opinion, does your relative experience worrying/suspicious beliefs about you/other people or events?</b>											
Yes						No					
<b>2b. To what extent, does this upset you?</b>											
0	1	2	3	4	5	6	7	8	9	10	
Not at all upset						Extremely upset					
<b>3a. In your opinion, does your relative experience ongoing difficulties with hallucinations (e.g. hearing voices and/or seeing things) that other people cannot hear and/or see?</b>											
Yes						No					
<b>3b. To what extent, does this upset you?</b>											
0	1	2	3	4	5	6	7	8	9	10	
Not at all upset						Extremely upset					
<b>4a. In your opinion, does your relative have difficulties with their motivation, getting up in the mornings and making plans for their day?</b>											
Yes						No					
<b>4b. To what extent, does this upset you?</b>											
0	1	2	3	4	5	6	7	8	9	10	
Not at all upset						Extremely upset					

<b>5a. In your opinion, does your relative have difficulties with low mood?</b>										
Yes					No					
<b>5b. To what extent, does this upset you?</b>										
0	1	2	3	4	5	6	7	8	9	10
Not at all upset									Extremely upset	
<b>6a. In your opinion, does your relative have any other difficulties? If yes, please specify.</b>										
Yes					No					
<b>6b. To what extent, does this upset you?</b>										
0	1	2	3	4	5	6	7	8	9	10
Not at all upset									Extremely upset	
<b>7. Would you like to understand more about mental health medications?</b>										
Yes					No					

# **EXPERIENCE OF CAREGIVING INVENTORY** (*male patient*)

The following statements commonly apply to persons who care for relative or friends with a serious mental illness. We would like you to read each statement and decide how often it has applied to you over the **PAST ONE MONTH**.

If it has **never** happened or **rarely** happened you would CIRCLE the number 0 or 1. If it has happened **sometimes**, then you would CIRCLE the number 2. If it has happened **often** or seems to have happened **nearly always**, then you would CIRCLE the number 3 or 4.

It is important to note that there are no right or wrong answers. Also it is best not to spend too long on any one statement. Often your first reaction will usually provide the best answer. While there seem to be a lot of statements, you will find that it won't take more than a moment or so to answer each one.

**During the past month** how often have you thought about:

	<i>Never</i>	<i>Rarely</i>	<i>Some- Times</i>	<i>Often</i>	<i>Nearly Always</i>
1. Your covering up his illness.....	0	1	2	3	4
2. Feeling unable to tell anyone of the illness.....	0	1	2	3	4
3. His difficulty looking after money.....	0	1	2	3	4
4. Having to support him.....	0	1	2	3	4
5. What life he might have had.....	0	1	2	3	4
6. His risk of committing suicide.....	0	1	2	3	4
7. I have learnt more about myself.....	0	1	2	3	4
8. I have contributed to others understanding of the illness.....	0	1	2	3	4
9. Being unable to do the things you want to do.....	0	1	2	3	4
10. How health professionals do not take you seriously.....	0	1	2	3	4
11. His dependence on you.....	0	1	2	3	4
12. Helping him to fill in the day.....	0	1	2	3	4
13. I have contributed to his wellbeing.....	0	1	2	3	4
14. That he makes a valuable contribution to the household.....	0	1	2	3	4
15. The effect on your finances if he becomes more seriously ill..	0	1	2	3	4
16. Dealing with psychiatrists.....	0	1	2	3	4
17. Him always being at the back of your mind.....	0	1	2	3	4
18. Whether you have done something to make him ill.....	0	1	2	3	4
19. That he has shown strengths in coping with his illness.....	0	1	2	3	4
20. I have become more confident in dealing with others.....	0	1	2	3	4
21. How family members do not understand your situation.....	0	1	2	3	4
22. That he is good company.....	0	1	2	3	4
23. I have become more understanding of others with problems..	0	1	2	3	4
24. How he thinks a lot about death.....	0	1	2	3	4
25. His lost opportunities.....	0	1	2	3	4
26. How to deal with mental health professionals.....	0	1	2	3	4
27. Feeling unable to have visitors at home.....	0	1	2	3	4
28. How he gets on with other family members.....	0	1	2	3	4
29. Backing him up when he runs out of money.....	0	1	2	3	4



	<i>Never</i>	<i>Rarely</i>	<i>Some- Times</i>	<i>Often</i>	<i>Nearly Always</i>
30. How family members do not understand the illness.....	0	1	2	3	4
31. How he deliberately attempts to harm himself.....	0	1	2	3	4
32. I have become closer to some of my family.....	0	1	2	3	4
33. I have become closer to friends.....	0	1	2	3	4
34. I share some of his interests.....	0	1	2	3	4
35. I feel useful in my relationship with him.....	0	1	2	3	4
36. How health professionals do not understand your situation....	0	1	2	3	4
37. Whether he will ever get well.....	0	1	2	3	4
38. Feeling the stigma of having a mentally ill relative.....	0	1	2	3	4
39. How to explain his illness to others.....	0	1	2	3	4
40. Others leaving home because of the effect of his illness.....	0	1	2	3	4
41. Setting him up in accommodation.....	0	1	2	3	4
42. How to make complaints about his care.....	0	1	2	3	4
43. I have met helpful people.....	0	1	2	3	4
44. I have discovered strengths in myself.....	0	1	2	3	4
45. Feeling unable to leave him home alone.....	0	1	2	3	4
46. The effect of the illness on children in the family.....	0	1	2	3	4
47. The illness causing a family breakup.....	0	1	2	3	4
48. Him keeping bad company.....	0	1	2	3	4
49. How his illness effects special family events.....	0	1	2	3	4
50. Finding out how hospitals or mental health services work.....	0	1	2	3	4
51. Doctor's knowledge of the services available to families.....	0	1	2	3	4
52. The difficulty getting information about his illness.....	0	1	2	3	4

***During the past month*** how often have you thought about him being:

53. Moody.....	0	1	2	3	4
54. Unpredictable.....	0	1	2	3	4
55. Withdrawn.....	0	1	2	3	4
56. Uncommunicative.....	0	1	2	3	4
57. Not interested.....	0	1	2	3	4
58. Slow at doing things.....	0	1	2	3	4
59. Unreliable about doing things.....	0	1	2	3	4
60. Indecisive.....	0	1	2	3	4
61. Irritable.....	0	1	2	3	4
62. Inconsiderate.....	0	1	2	3	4
63. Behaving in a reckless way.....	0	1	2	3	4
64. Suspicious.....	0	1	2	3	4
65. Embarrassing in appearance.....	0	1	2	3	4
66. Behaving in a strange way.....	0	1	2	3	4

**Thank you very much for answering these questions**



Please list in rank-order the **three** most important factors that you believe caused his problems/illness

1. \_\_\_\_\_

2. \_\_\_\_\_

3. \_\_\_\_\_

## CLINICAL OUTCOMES IN ROUTINE EVALUATION - CORE-10

### IMPORTANT – PLEASE READ THIS FIRST

This form has 10 statements about how you have been OVER THE LAST WEEK.

Please read each statement and think how often you felt that way last week. Then tick the box which is closest to this.

*Over the last week...*

		Not at all	Only occasionally	Sometimes	Often	Most or all of the time
1	I have felt tense, anxious or nervous	0	1	2	3	4
2	I have felt I have someone to turn to for support when needed	4	3	2	1	0
3	I have felt able to cope when things go wrong	4	3	2	1	0
4	Talking to people has felt too much for me	0	1	2	3	4
5	I have felt panic or terror	0	1	2	3	4
6	I made plans to end my life	0	1	2	3	4
7	I have had difficulty getting to sleep or staying asleep	0	1	2	3	4
8	I have felt despairing or hopeless	0	1	2	3	4
9	I have felt unhappy	0	1	2	3	4
10	Unwanted images or memories have been distressing me	0	1	2	3	4

### Patient Health Questionnaire (PHQ-9)

Over the <i>last 2 weeks</i> , how often have you been bothered by any of the following problems?	Not at all	Several days	More than	Nearly every
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself in some way	0	1	2	3

TOTAL:

--	--	--	--

### Generalised Anxiety Disorder Questionnaire (GAD-7)

Over the last two weeks, how often have you been bothered by the following problems?	Not at all	Several Days	More than half	Nearly every
1 Feeling nervous, anxious or on edge	0	1	2	3
2 Not being able to stop or control worrying	0	1	2	3
3 Worrying too much about different things	0	1	2	3
4 Trouble relaxing	0	1	2	3
5 Being too restless that it is hard to sit still	0	1	2	3
6 Becoming easily annoyed or irritable	0	1	2	3
7 Feeling afraid as if something awful might happen	0	1	2	3

SUB TOTAL:

--	--	--	--

**TOTAL**

If you checked off *any* problems, how *difficult* have these problems made it for you to do your work, take care of things at home, or get along with other people?

<b>Not difficult at all</b> _____
<b>Somewhat difficult</b> _____
<b>Very difficult</b> _____
<b>Extremely difficult</b> _____

**The Warwick-Edinburgh Mental Well-being Scale  
(WEMWBS)**

**Below are some statements about feelings and thoughts.**

**Please tick the box that best describes your experience of each over the last 2 weeks**

<b>STATEMENTS</b>	<b>None of the time</b>	<b>Rarely</b>	<b>Some of the time</b>	<b>Often</b>	<b>All of the time</b>
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been feeling interested in other people	1	2	3	4	5
I've had energy to spare	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling good about myself	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been feeling confident	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5
I've been feeling loved	1	2	3	4	5
I've been interested in new things	1	2	3	4	5
I've been feeling cheerful	1	2	3	4	5

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

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## BRIEF COPE INVENTORY

*This section asks how you have typically tried to deal with difficulties you, a friend, partner or relative may be experiencing. Below is a list of things you may have done. Please decide if you have used each strategy **in the LAST 3 MONTHS** and if so how often you have used it.*

### HOW OFTEN HAVE YOU:

0	I have never done this
1	I have rarely done this
2	I have sometimes done this
3	I have done this a lot

1. Gone to the cinema or watched TV, to think about the problem less	0	1	2	3
2. Drank alcohol or took drugs in order to think about the problem less	0	1	2	3
3. Pretended the problem hadn't really happened	0	1	2	3
4. Given up your attempts to get what you wanted	0	1	2	3
5. Taken alcohol or drugs to help you get through the problem	0	1	2	3
6. Turned to work or other substitute activities to take your mind off the problem	0	1	2	3
7. Just gave up trying to solve the problem	0	1	2	3
8. Refused to believe the problem had happened	0	1	2	3



## *Systematic Review*

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# **A systematic review of group interventions to support caregivers of people with psychosis**

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*Supervised by:*

*Dr Juliana Onwumere &*

*Dr Suzanne Jolley*

## **Abstract**

### **Background**

Carers perform an integral role in supporting service users with psychosis. However, they can experience substantial distress and burden associated with their caregiving roles, which adversely impacts their own mental and physical health, and through the quality of the caregiving relationship, that of the person they care for. As a consequence, support to caregivers in their own right is now being highlighted as a mental health and social care priority, although implementation is as yet limited. Group interventions for carers of people with psychosis might be a cost-effective way to improve access and caregiver outcomes, but no review of the literature evaluating the impact of such groups on carer outcomes has been undertaken to date.

### **Objectives**

The first objective of the current review was to evaluate the range of group interventions for carers in psychosis and their effectiveness in terms of carer outcomes. The second objective was to assess the methodological quality of group intervention studies, with a view to informing future evaluations.

### **Method**

A systematic review was undertaken, considering studies which evaluate group interventions for carers in psychosis against a comparison/control group and report carer outcomes. Fifty-two studies met inclusion criteria and were included in the review. As a wide range of outcome measures was employed, it was not possible to meaningfully compare the effectiveness of different interventions against each other. Measures were coded according to ten main outcome categories identified. The methodological quality of studies was assessed using the Clinical Trial Assessment Measure (CTAM).

### **Results**

The review identified six main types of group interventions offered across the 52 studies, which were evaluated with 103 different carer-specific outcomes.

Over half the studies reported a statistically significant positive effect on at least one carer outcome category. Group interventions were found to be most effective on outcomes relating to family functioning, followed by carer attitudes and beliefs about the illness, burden, and knowledge of the illness. In general, the methodological quality of studies was low, with only 25% of studies rated as adequate according to CTAM criteria, further limiting the conclusions to be drawn from the data.

## **Conclusions**

Group interventions appear to have a positive impact on carer outcomes, with the best evidence emerging for psychoeducation and peer support groups. However, the positive direction of results from multiple family groups, relatives groups, web-based groups and yoga interventions suggests further research should be undertaken to more firmly establish the benefits of these modalities. The review suggests clinical recommendations to aid those developing group interventions for carers in psychosis and outlines directions for future research. This includes recommendations to improve trial conduct and reporting in relation to masking and randomisation, as well as better definition of control groups, assessment of treatment adherence, and use of specific primary carer outcomes. The longer-term benefits of group treatments and the components of effective treatments also require further investigation.

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# 1. Introduction

## 1.1 Prioritising the needs of carers in psychosis

Psychotic disorders such as schizophrenia involve unusual experiences including delusions, hallucinations and disorganization, as well as negative symptoms affecting motivation, emotional expression and socialization. The World Health Organization reported a point prevalence of 0.4% for schizophrenia (Global Burden of Disease [GBD] 2000), and highlighted that active psychosis ranked as the third most disabling condition among physical and mental health conditions (Üstün et al. 1999). An update of the GBD study (2010) indicates that schizophrenia continues to exert significant global burden (Whiteford et al., 2013). As a chronic and debilitating condition with an early age of onset, psychotic disorders carry enormous personal, financial and societal costs (Almond et al., 2004; Knapp et al., 2004).

It is widely acknowledged that the negative impact of psychosis extends to families (Kuipers, 2010). Caring for a person with psychosis can levy a heavy burden on caregivers (Awad & Voruganti, 2008) and is associated with higher rates of anxiety and depression, increased worry and strain, diminished social networks and increased isolation compared to non-caregiving peers (Hayes et al., 2015). Thus *“family members are as much victims of severe mental disorders as patients themselves”* (McFarlane and Cook: (2007, p. 196). Carers in psychosis deserve special attention, owing not only to the significant impact of caregiving, but also because they fulfil a vital role in improving outcomes for patients, with substantial clinical and financial implications. Considerable research has shown the importance of carers in providing long-term support to patients; for example, positive family environments are associated with reduced risk of relapse (Lee et al., 2014). Prevalence rates of psychosis in the United Kingdom (UK) have led to corresponding estimates of up to 120,000 people at any one time being in unpaid primary caregiving roles for adults with psychosis (Kuipers, 2010). Informal carers are reported to save



the public purse approximately £1.24 billion a year (Schizophrenia Commission, 2012).

Recognizing the pivotal role of carers in social health care (Albert & Simpson, 2015), the recent UK Care Act (2014) highlighted the importance of identifying and addressing caregiver needs. The updated national guidance for the treatment of psychosis in adults (National Institute for Health and Care Excellence, NICE, 2014) also recommended, for the first time, that caregivers be offered support in their own right, to help them understand the illness, to engage in active coping and effective problem solving, and to care for their own wellbeing in the context of demanding caring roles. Despite research indicating that interventions with carers can positively impact on their needs arising from the caregiving role (e.g. Kuipers, 2011; Roddy et al., 2014), implementation remains poor (Bucci et al., 2016). Kuipers (2010) contends that *“caregivers are nobody’s job”*, as psychosis services focus on service users’ needs and mental state. Kuipers states that services do not currently see *“caregivers as individuals, caught up in a difficult and frightening process, who themselves need support, help and information”*; support to carers unfortunately continues to be viewed as ancillary. A strong argument therefore exists for better prioritising the needs of carers, and improving implementation and access to support which can enable carers to address their own needs and help them cope better in their caregiving roles.

## **1.2 Main interventions offered to carers in psychosis**

The importance of supporting caregivers to develop adaptive coping strategies and illness appraisals has been highlighted in cognitive models of caregiving (Kuipers et al., 2010; Mackay & Pakenham, 2012). When asked how they would like to be helped, carers typically highlight the importance of receiving relevant information about treatment, being included in care planning and having a clear understanding of how to respond to crises (Askey et al, 2009; Cree et al., 2015). In addition, studies have shown that improving carers’ understanding of psychosis can positively impact their affect (Kuipers et al., 2007).

National clinical guidelines stipulate that carer should be provided “*written and verbal information in an accessible format about diagnosis and management of psychosis and schizophrenia*” (NICE, 2014, p. 178). In addition, the updated Schizophrenia Patient Outcomes Research Team (PORT, 2010) offer similar recommendations in the United States, including that “key elements of effective family interventions include illness education, crisis intervention, emotional support and training in how to cope with illness symptoms and related problems” (Kreyenbuhl et al., 2010, p. 99). It is also suggested that family interventions last at least 6–9 months.

The late 1990’s saw the emergence of a strong consensus between international experts about the key aspects of effective family interventions. Formalized by the World Schizophrenia Fellowship (1998), all successful family programmes were thought to share the following common elements:

- Listen to families and treat them as equal partners in treatment planning and delivery
- Explore family members’ expectations of the treatment programme and for the client
- Coordinate all elements of treatment and rehabilitation to ensure that everyone is working towards the same goals in a collaborative way
- Be flexible in meeting the needs of the family
- Pay attention to the social as well as the clinical needs of the client
- Provide relevant information for the client and family at appropriate times
- Provide optimum medication management
- Provide the family with easy access to a professional (in case of need) if the work with the family ceases.
- Provide an explicit crisis plan and professional response
- Assess the family’s strengths and limitations in their ability to support the client
- Help resolve family conflict through taking a sensitive response to emotional distress

- Address feelings of loss
- Help improve communication among family members
- Provide training for the family in structured problem-solving techniques
- Encourage the family to expand their social support networks, e.g. participation in multifamily groups or family support organisations

A variety of evidence-based family intervention models have evolved over the past 30 years, to assist patient recovery and help reduce relapse rates (Pharaoh et al., 2010) and address carers' needs for clinical information and guidance, and ongoing support. This includes family intervention in psychosis (Flp), professionally-led family psychoeducation and peer-led support, as detailed below.

### **1.2.1 Family intervention in psychosis (Flp)**

A cognitive-behavioural family intervention model was developed following seminal research showing an increased risk of relapse in schizophrenic patients living with critical / overinvolved relatives, i.e. – relatives high in 'expressed emotion' (EE) (Brown and Rutter, 1966; Brown et al., 1972). Family interventions in psychosis (Flp) integrates psychoeducation with a structured family approach employing cognitive-behavioural techniques, and are available in manualised formats (e.g. Barrowclough & Tarrier, 1992; Kuipers et al., 2002). Reviews of the evidence base for Flp confirm its efficacy in reducing patients' relapse and readmission rates as well as improving medication compliance and social functioning (Pfammatter et al. 2006; Pharaoh et al. 2010) and conclude that Flp should be offered to people with schizophrenia who are in contact with carers (Onwumere et al., 2011; NICE, 2014), including at first-episode (Bird et al., 2010) and for more complex presentations (Onwumere et al., 2016).

### **1.2.2 Family psychoeducation (FPE)**

Anderson, Hogarty, and Reiss (1980) – the original proponents of FPE for schizophrenia – developed a model which involves engaging with family and

client, providing illness education, evidence-based recovery and crisis-support guidelines and problem-solving strategies. Several reviews highlight the effectiveness of FPE as an adjunct to medication management for patient relapse and rehabilitation in schizophrenia, and conclude that family psychoeducation should be a central component of effective treatment of schizophrenia (Lucksted et al., 2012; Sin & Norma, 2013). However, McFarlane et al. caution that the term 'psychoeducation' can be misleading, and is not limited to provision of information, but *"includes many cognitive, behavioural and supportive therapeutic elements...sharing key characteristics with other types of family interventions"* (2003, p.224). They suggest that several treatment approaches have further developed FPE models, as described briefly below.

### ***Behavioural Family Management (BFM)***

Developed by Falloon et al. (1982), BFM involves a behavioural analysis of the needs of the family and provision of single-family home treatment sessions which focus on education about the illness as well as communication and problem-solving skills training. The most behavioural of the FPE approaches, the model begins by emphasizing the strengths of family members striving to cope with the challenges of caring for a mentally ill family member.

### ***Relatives Groups***

Leff et al. (1989) developed a model of family intervention which aims to enhance family coping through individual family psychoeducation sessions combined with biweekly relatives groups, excluding patients, which focus on support and problem-solving. A unique goal of this model is to encourage interactions between carers assessed as low and high in EE, so as to facilitate the modelling of low-EE responses.

### ***Multiple Family Groups (MFG)***

The MFG approach arose in the 1960's, instigated by efforts to develop psychosocial treatments for inpatients (e.g. – Detre et al., 1961; Laqueur et al., 1964). MFG refers to a specific FPE approach which integrates aspects of the above models, combining psychoeducation about the illness with

communication and problem-solving skills training, crisis intervention and family support (McFarlane, 2002). The MFG intervention manual (McFarlane et al., 1991) outlines three main phases: the first phase, focusing on preventing relapse, comprises single-family joining sessions with a therapist and a multifamily educational workshop, followed by group meetings for 90 minutes bi-weekly which focus on family problem-solving. In the second phase, the emphasis shifts to fostering the social and vocational rehabilitation of the patient, and the third phase focuses on strengthening the social networks of patients and their family members through group problem-solving, and out-of-group socialising.

### **1.2.3 Peer support**

More recent innovations in carer interventions include approaches moving from professional-led interventions to self-help activity for families of people with severe mental illness (Cook et al., 1999). The US Family-to-Family Education Programme (FFEP), in which trained family member volunteers facilitate a 12-week intervention, provides education about the illness and treatment, problem-solving, communication, coping and self-care skills. Furthermore, FFEP provides a forum for peer support and information exchange between families with shared experience of caring for a mentally ill relative, and also promotes advocacy efforts for patients and their families. Dixon et al. (2001, 2004) found that FFEP is effective in increasing carers' knowledge, empowerment and self-care, and decreasing subjective burden.

## **1.3 Group-based interventions**

Carers in psychosis are up to ten times more isolated than non-carer peers (Hayes et al., 2015) and carers in other long-term conditions (Magliano et al., 2006). In addition, the Schizophrenia Commission (2012) points to issues of poor access to family interventions, highlighting that scarce therapy resources are unable to meet current demand. In the UK alone, evidence suggests that less than 2% of eligible families are offered family interventions, and only

about 1% obtain it (Haddock et al., 2014). In addition, given the importance of health interventions, including family interventions, to be time-efficient and cost effective (Cohen et al., 2008; Onwumere et al., 2016), group interventions offer a number of practical advantages in supporting caregivers. By targeting greater numbers of caregivers, and optimising valuable clinician resources, group formats may increase equitable access and offer more economically viable interventions. Thus a strong case can be made for providing evidence-based group interventions, both to address the social isolation of carers in psychosis and improve their access to professional help. However, a crucial first step relates to establishing the impact of group-based interventions and understanding the components of effective groups.

Finally, group formats may also confer a number of psychosocial benefits for carers. In addition to reducing the stigma commonly experienced by carers in psychosis (Cazzullo et al., 1989), groups also provide opportunities for sharing caregiving experiences (Kuipers, 2010), as well as for exchange of information which promotes self-understanding (Citron et al., 1999). These opportunities for interpersonal learning and the rehearsal of coping strategies can help increase feelings of purpose, self-efficacy, and self-worth (Heller et al., 1997). Seminal research examining the mechanisms of change in therapeutic groups (e.g. – Lieberman et al., 1979; Yalom, 1985) highlight valuable aspects of group formats, including group cohesiveness and universality of experience, or the “we-are-not-alone” phenomenon (Atwood & Williams, 1978). Cathartic processes such as grieving for unfulfilled expectations and the loss of relatives as they were before illness, as well as hope instillation by witnessing the coping of others with similar problems, can also be important aspects. Moreover, group formats can encourage altruism, which in keeping with the helper-therapy principle, suggests that those who help are helped most (Riessman, 1965). It is also suggested that group members may be more amenable to honest reflections about their behaviour from peers compared to others (e.g. staff) (Lidz, 1973; p. 121).

## **1.4 Carer-specific outcomes in the family interventions literature**

Despite a comprehensive literature highlighting the significant carer burden and distress associated with psychosis, the *“raison d’être of evidence-based family interventions...continues to be the reduction of the patient’s vulnerability to and risk of relapse”* (Onwumere et al., 2014, p. 212). A common criticism of the evidence base for FI is its primary focus on patient outcomes and neglect of carer outcomes (Barbato & D’Avanzo, 2000; Grice et al., 2009). Although FI effectively reduces high EE levels and burden in carers (Giron et al. 2010; Pfammatter et al. 2006; Pharoah et al. 2010; Pousa et al., 2011), carer outcomes do not receive adequate attention in FI studies. A recent review highlights that carer-specific outcomes continue to be poorly evaluated and documented in the FI literature (Lobban et al. 2013).

## **1.5 Rationale for current review**

Enhancing carer support is an important issue, particularly in light of recent UK treatment guidance, which prioritises caregiver wellbeing (NICE guidelines 2014; UK Care Act 2014). Lobban et al. (2013) reviewed randomised control trials (RCTs) of interventions reporting outcomes for relatives of people with psychosis. However there has been a lack of data looking specifically at group intervention studies evaluating carer outcomes. The current review aims to facilitate a better understanding of the range of group interventions offered to carers in psychosis, along with the evidence regarding their effectiveness on carer outcomes. It also aims to evaluate the methodological quality of studies and explore whether particular interventions offer comparative advantages for carers.

## **2. Method**

### **2.1 Literature search**

Systematic searches of four databases were performed to identify relevant treatment studies published up to January 2016. These included EMBASE (1974 to January 2016), MEDLINE (R) (1946 to January 2016), PsycINFO (1806 to January 2016), and the Cochrane Library. Reference lists of identified papers were then reviewed to find additional appropriate studies. The reference list of a recent review of RCTs reporting outcomes for carers of people with psychosis (Lobban et al., 2013) was also explored for any relevant studies.

The search strategy combined all 3 categories, each employing a variety of search terms, as follows:

1. Psychosis OR schizophrenia OR psychotic dis\* OR psychotic ill\* OR hearing voices OR hallucination\* OR delusion\*
2. Caregiver\* OR carer\* OR famil\* OR relative\* OR parent\* OR partner\* OR spouse\* OR sibling\*
3. Group intervention\* OR group psychoeducat\* OR group therap\* OR group support OR group train\*

The search returned papers published in any language which contained at least one term from each category. Titles and abstracts were reviewed manually to identify potential studies. Conference abstracts were excluded at this stage. The full texts of eligible papers were reviewed for inclusion, data extraction and quality assessment.

### **2.2 Inclusion and exclusion criteria**

Papers were included in the review if they:

1. Evaluate a group intervention to support carers of people with psychosis
2. Report quantitative outcome measures for carers
3. Assess a control or comparison group



Papers were excluded if they:

1. Do not evaluate a primarily group intervention, i.e. – studies were excluded if they offered a small group component within a wider package of social/ family interventions (e.g. Leff et al., 1982, 1985) or evaluated carer ‘associations’ formed after an intervention (e.g. Monking, 1994)
2. Do not explicitly state that the intervention is in a group format (e.g. Das et al, 2006).
3. Include carers of patients with disorders other than psychosis (e.g. major affective disorders)
4. Report only service user outcomes and/or qualitative carer outcomes
5. Single case studies, case series or discussion articles
6. Unpublished dissertations and papers
7. Studies unavailable because they have not been translated into English

The author (PK) assessed the relevance of papers based on the above criteria, and queries were resolved through discussion with supervisors JO and SJ.

## **2.3 Data extraction**

To extract data relevant to the review questions, a form was developed, based on the Cochrane Collaboration’s data extraction template (2011) and the quality assessment tool (see Appendix 1). Information from papers reporting data at varying time points of the same study was assimilated.

## **2.4 Quality Assessment**

The methodological quality of each selected paper was assessed using the Clinical Trial Assessment Measure (CTAM, Tarrier & Wykes, 2004; see Appendix 2). The CTAM, devised to assess the methodological rigour and validity of RCTs, was chosen as the quality assessment tool in this review since all papers included were intervention studies with control/comparison groups. The total CTAM score is derived from ratings on six subscales

assessing potential sources of bias in studies, including recruitment and size of the sample, randomization procedures, assessment of outcomes, analysis, control groups and treatment description and fidelity. Wykes et al. (2008) suggest that a CTAM score of 65 or above out of a maximum score of 100, demonstrates sufficient methodology. Although the validity of this cut-off is yet to be established, the CTAM has good inter-rater reliability and concurrent validity (Tarrier & Wykes, 2004). The CTAM enables comparison of studies in terms of methodological quality and has been used to evaluate clinical trials of family intervention in psychosis (Lobban et al., 2013), cognitive behaviour therapy (CBT) for schizophrenia (Tarrier & Wykes, 2004; Wykes et al., 2008) and cognitive remediation in schizophrenia (Wykes et al. 2011). To ensure reliable quality assessment using the CTAM in the present review, a sub-selection of papers (6%) was blind-rated by three raters (PK, JO and SJ) and ratings were discussed to achieve consensus.

## **2.5 Categorising outcome measures**

Many papers included in the review used a large variety of measures to assess outcomes in relatives, rendering it difficult to assess and compare the efficacy of studies. Using a similar approach to Lobban et al. (2013), carer measures were categorised into ten discrete clusters to facilitate an understanding of outcomes, as follows:

- 1.) Carers' knowledge acquisition about the illness
- 2.) Carers' attitudes, opinions and beliefs about the illness and attribution of patient symptoms
- 3.) Carers' need for, use of and satisfaction with health care and support services
- 4.) Carers' subjective and objective burden (including number of contact hours, distress relating to patient behaviour, perceived control over patients' symptoms and stigma)
- 5.) Carers' psychosomatic health (including general psychopathology, state and trait anxiety, depression, psychological distress, stress, somatic symptoms and quality of life)

- 6.) Carers' perception of social support (including persons available as support and satisfaction with available support)
- 7.) Carers' coping and self-efficacy (including self-care and general functioning)
- 8.) Quality of caregiving relationship (including expressed emotion, rejecting attitudes towards the patient, experience of caregiving)
- 9.) Family functioning (including family satisfaction and family atmosphere)
- 10.) Family conflict

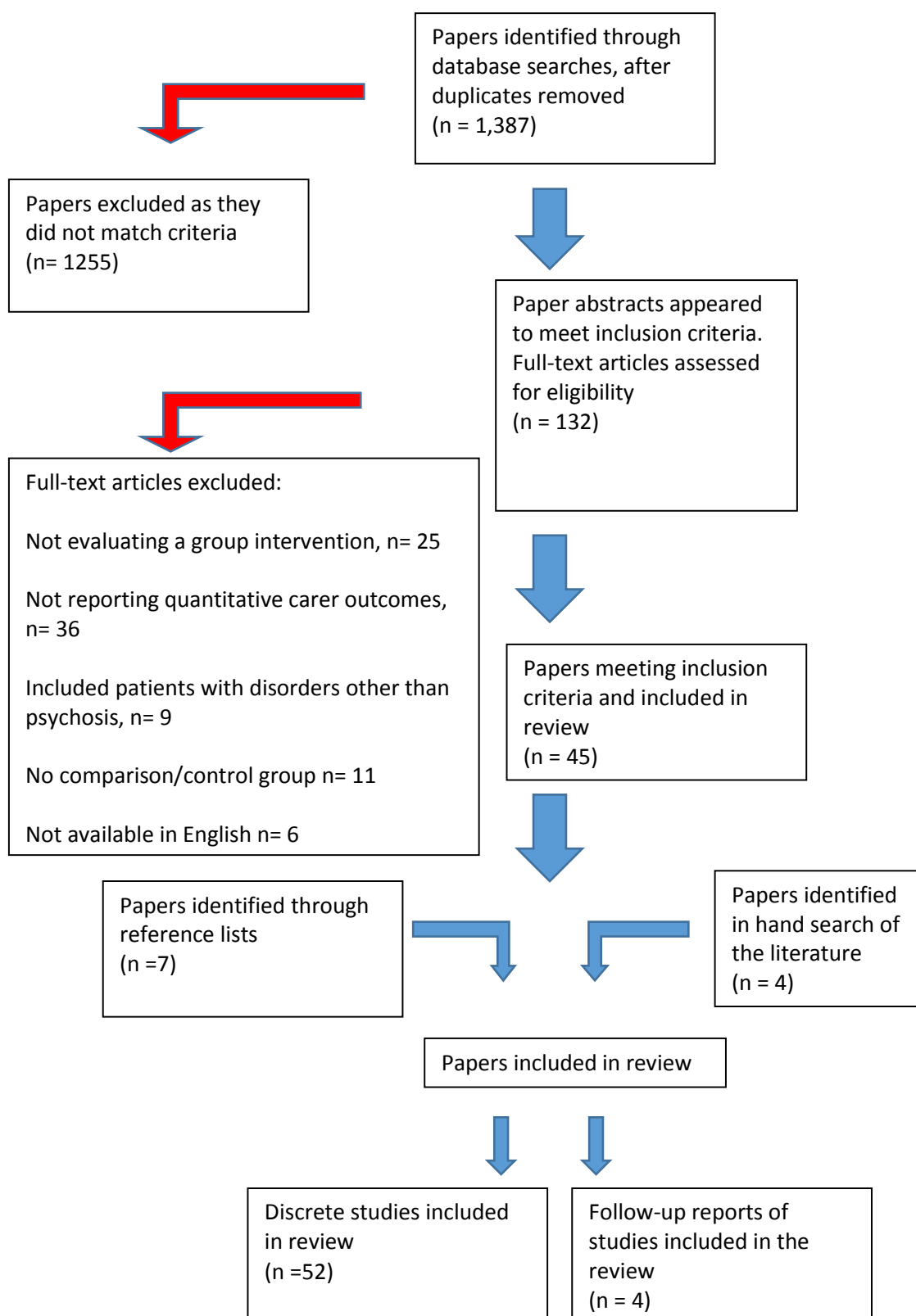
To analyse treatment efficacy, studies were coded as effective or ineffective on each category for which outcomes were reported. If there were multiple measures used in one category with differing results, then the study was coded as inconclusive. For instance, in a study by Martin-Carrasco et al. (2016), carer depression was measured using the CES-D and the GHQ-9, with results indicating the treatment was effective on the former outcome but ineffective on the latter. This study was thus coded as inconclusive with respect to outcome category 5 (carers' psychosomatic health).

## **3. Results**

### **3.1 Search results**

The search identified 1387 papers after duplicates were removed. Manual review of titles and abstracts identified 132 papers for full text review. Of these, 45 papers met criteria for inclusion and 87 were excluded, mostly because they did not report quantitative carer outcomes (n=36) or did not evaluate a group intervention (n=25). One paper which studied both carers in psychosis and bipolar disorder was included as carer outcomes were evaluated separately for each disorder (Navidian et al., 2012). Seven additional studies were identified through hand searching reference lists, and another four through additional hand searches of the literature. Of the 56 papers identified for review, there were 52 distinct studies and 4 follow-up reports. Figure 1 shows the process of the systematic search.

Figure 1: PRISMA (2009) flow diagram of systematic review process



### 3.2 Sample characteristics

The 52 papers included a total of 9038 carer participants, with sample sizes ranging from 10 – 3,092 ( $M=173.81$ ,  $SD=443.43$ , median=75). Over 42% of studies were conducted in Hong Kong and the USA (11 studies each), followed by the UK (5 studies) and Iran (4 studies). The remaining 21 studies were conducted in 13 different countries including Australia, Canada, Chile, China, Denmark, Finland, Germany, Greece, India, Italy, Japan, Malaysia, Spain and Taiwan. Thirty-one studies offered the intervention only to carers, (*coded 1* under 'Group Participants' in Table 1). Twenty studies included patients in the intervention, either with carers in all sessions ( $n=8$ , *coded 2*), in separate sessions ( $n=6$ , *coded 3*), or with carers in some sessions ( $n=5$ , *coded 4*). One study (Rotondi et al., 2005) offered 3 distinct online groups in their web-based intervention, providing 2 separate therapy groups for carers and patients, and a third group combined carers and patients. Details of each study are presented in table 1 below.

Table 1. Characteristics of studies included in the review

<b>Study authors &amp; year</b>	<b>Location</b>	<b>N</b>	<b>Control group</b>	<b>Group Participants</b>	<b>Max per group</b>	<b>Intervention</b>	<b>No. of sessions</b>	<b>Duration &amp; frequency of sessions</b>	<b>Key Carer Outcomes</b>	<b>Follow ups</b>	<b>CTAM total</b>
Abramowitz & Coursey, 1989	USA	48	Waiting list (W/L) control	1	17	Psychoeducation	6	2 hours, weekly	3,4,5,7, 8	-	17
Birchwood et al., 1992	UK	94	2 active controls	1	-	Psychoeducation	4	Weekly	1,2,4,5, 7	6 months	25
Bradley et al., 2006	Australia	59	TAU	2	14	MFG	24 MFG meetings	Fortnightly for 12 months	4	18 months	59
Buchkremer et al., 1995	Germany	151	W/L control	1	15	Relatives group	26	Fortnightly	8,9,10	18 months, 24 months, 36 months	46
Calvo et al., 2014	Spain	55	Active control	3	-	MFG	12	1.5 hours, fortnightly	9	-	70

Carra et al., 2007	Italy	101	Active control + W/L control	1	9	Psychoeducation	24	1.5 hours, weekly	4	12 months, 24 months	75
Chan et al., 2009	Hong Kong	73	TAU	2	-	Psychoeducation	10	weekly	4,6,7	6 months, 12 months	63
Cheng & Chang, 2005	Hong Kong	64	TAU	1	8	Psychoeducation	10	2 hours, weekly	4,6,7	-	45
Chien, 2008	Hong Kong	68	TAU	4	11	Psychoeducation	18	2 hours, fortnightly	3,4,9	12 months	78
Chien & Chan, 2004	Hong Kong	96	TAU + Active control	4	11	Peer support	12	2 hours, fortnightly	3	12 months	65
Chien & Chan, 2013	Hong Kong	135	TAU + Active control	4	12	Peer support	14	2 hours, every 2-3 weeks	3,6,9	12 months, 24 months	88



Chien, Chan, Morrissey & Thompson, 2005	Hong Kong	96	TAU + Active control	4	11	Peer support	12	2 hours, fortnightly	3, 9	6 months	88
Chien, Chan & Thompson, 2006	Hong Kong	96	TAU + Active control	3	-	Peer support	12	2 hours, fortnightly	3, 4	6 months, 18 months	85
Chien, Norman & Thompson, 2004	Hong Kong	48	TAU	1	-	Peer support	12	2 hours, weekly	3, 4, 9	3 months	63
Chien & Thompson, 2013	Hong Kong	106	TAU + Active control	2	-	Peer support	14	2 hours, every 2-3 weeks	3, 9	18 months, 36 months	85
Chien, Thompson & Norman, 2008	Hong Kong	76	TAU	1	-	Peer support	12	2 hours, weekly	3, 4, 6, 9	12 months	58

Chien & Wong, 2007	Hong Kong	84	TAU	4	-	Psychoeducation	18	2 hours, fortnightly	4, 9	12 months	54
Chou et al., 2002	Taiwan	84	W/L control	1	12	Peer Support	8	1.5 hours, weekly	4,5, 7	1 month	35
Cozolino et al., 1988	USA	29	W/L control	3	10	Psychoeducation	1	3 hours	1, 2, 3, 4, 8, 10	-	35
Fallahi et al., 2014	Iran	71	TAU	1	-	Psychoeducation	4	2 hours, weekly	4	1 month	56
Fiorillo et al., 2011	Italy	236	TAU	3	-	Psychoeducation	12	1.5 hours, 3 sessions a months for 4 months	2	-	47
Glynn et al., 2010	USA	42	Archival data (TAU)	1	6	Web-based therapy group	36	60-minutes, weekly for first 6 months, fortnightly for next 6 months	5, 6, 8	-	26

Gutierrez-Maldonado et al., 2007	Chile	45	TAU	1	9	Psychoeducation	17	1.5 hours, Weekly	4	-	32
Gutierrez-Maldonado et al., 2009	Chile	45	TAU	1	-	Psychoeducation	18	1.5 hours, Weekly	2, 5	-	22
Hazel et al., 2004	USA	97	TAU	2	8 families	MFG	36	90 minutes, bimonthly in 1 <sup>st</sup> year, monthly in 2 <sup>nd</sup> year	5, 6, 7	24 months	46
Kane et al., 1990	USA	49	Active control	1	8	Psychoeducation	4	2 hours, weekly	1, 5, 6, 8	-	23
Kopelowicz et al., 2003	USA	92	TAU	3	6	Psychoeducation	12	Weekly	2, 4, 8	6-months	69
Leff et al., 1989, 1990	UK	23	Active control	1	-	Relatives' group	18	1.5 hours, fortnightly over 9 months	8	2 year	46
Liberman et al., 1984	USA	53	TAU + Active control	2	3 families	MFG	9	2 hours, weekly	1, 8, 10	-	17

Martin-Carrasco et al., 2016	Spain	223	TAU	1	-	Psychoeducation	12	90-120 minutes, weekly	4, 5	8 months	67
Mentis et al., 2014	Greece	510	TAU	-	-	Peer support	-	-	5	-	19
Merinder et al., 1999	Denmark	35	TAU	3	8	Psychoeducation	8	Weekly	1, 3, 8	12 months	71
McDonnell et al., 2003	USA	84	TAU	2	-	MFG	36	Bimonthly for first year, monthly for the second year	4, 6, 7	-	39
Montero et al., 2001, 2005, 2006	Spain	87	Active control	1	10	Relatives group	33 (12 month open group)	90 minutes, Weekly - first 6 months, fortnightly - next 3 months, monthly- last 3 months	1, 5, 8	5 years	64
Mueser et al., 2001	USA	528	Active control	2	20	Relatives group	24	1.5 hours, monthly	8	-	66

Navidian et al., 2012	Iran	50	TAU	1	9	Psychoeducation	4	2 hours, weekly	4	3 months	41
Paranthaman et al., 2010	Malaysia	109	TAU	1	-	Psychoeducation	5 lectures	1 hour, 5 lectures over 2 weeks	1, 4	3 months, 6 months	23
Perlick et al., 2011	USA	158	Active control	1	8	Peer support	1	75 minutes	4	-	68
Posner et al., 1992	Canada	55	W/L control	1	9 families	Psychoeducation	8	1.5 hours, weekly	1, 3, 5, 7, 8, 9	6 months	33
Rahmani et al., 2015	Iran	74	W/L control	1	37	Psychoeducation	8	1.5 hours, thrice weekly	2	-	55
Reid et al., 1993	UK	10	W/L control	1	5	Psychoeducation	5	3.5 hours, weekly	1, 4, 5, 8	-	23
Rotondi et al., 2005	USA	21	TAU	2, 3	-	Web-based therapy group(s)	Three separate online therapy groups	Bulletin board format for internet communication	4, 6	3 months, 6 months	38

Sharif, Shaygan & Mani, 2012	Iran	70	TAU	1	9	Psychoeducation	10	90 minutes, twice weekly	4	1 month	64
Shimodera et al., 2000	Japan	111	Active control	1	-	Psychoeducation	18	1 hour homes visits, fortnightly for 9 months	8	-	51
Smith & Birchwood, 1987	UK	40	Active control	1	-	Psychoeducation	4	60-90 minutes, weekly	1, 2, 4, 5	6 months	42
Sota et al., 2008	Japan	110	Comparison groups	1	20	Psychoeducation	5	2 hours, 5 sessions over 9 months	1	-	8
Stengard, 2003	Finland	197	Active control	1	-	Psychoeducation	8	2.5 hours, weekly	1, 4, 5, 8	6 months	32
Szmukler, Kuipers et al., 2003	UK	61	TAU	1	15	Relatives group	12	1.5 hours, fortnightly	5, 6, 7, 8	6 months	58
Varambally et al., 2013	India	29	W/L control	1	-	Yoga	12	45 minutes, thrice weekly	4, 5	3 months	33

Zhang, Yangling, et al., 1998	China	1037	TAU	1	40	Psychoeducation	14 lectures over 2 years	Lectures: 1 hour + additional group discussions	1, 4, 5	12months, 24 months	25
Zhang, et al., 1993, 1998	China	3092	TAU	1	40	Psychoeducation	16 lectures over 3 years	Lectures: 1 hour + additional group discussion	1, 4, 5	12 months, 24 months, 36 months	19
Zhao et al., 2015	China	31	TAU	2	-	Psychoeducation	12	2 hours, fortnightly	4, 5, 6	-	29

**Table key:**

**Group participants:** *1=carers only, 2=carers and patients together in all sessions, 3=carers and patients in separate sessions, 4=patients included in some sessions with carers*

**Key carer outcomes:** *1=knowledge acquisition, 2=attitudes/opinions/beliefs about illness, 3=need /use/ satisfaction with services, 4= burden, 5=psychosomatic health, 6=social support, 7=coping and self-efficacy, 8= quality of caregiving relationship, 9=family functioning, 10= family conflict*

### 3.3 Design

Most studies used a RCT design (n=36, 69%). One third of studies used non-randomised (quasi-experimental) designs (n=16), including prospective control studies, non-equivalent comparison groups design, and time series non-equivalent control groups design. Thirty-two studies (62%) included longitudinal outcomes following post-intervention assessments. Half of the 52 studies employed a treatment as usual (TAU) control group, nine studies used an active control group, and eight studies included a 'Waiting list' control group. Six studies included an active control and a TAU control, while one study had an active control and a waiting list control. Only one study used two active controls (Birchwood et al., 1992). One study attempted to compare three intervention groups, but as carers participated in more than one group, the groups could not be considered control groups (Sota et al., 2008). The interventions offered to 'active control' groups were either psychoeducation groups (n=6), individual family therapy (6), non-structured group interventions (n=2) or other educational interventions (e.g. postal or video education), (n=4).

### 3.4 Quality assessment

Each study's methodological quality was assessed using the CTAM (Tarrier & Wykes, 2004). Total scores out of 100 are presented above in Table 1. The mean CTAM score of the 52 studies was 47.81 (*SD* = 21.27, median = 46, range = 8 - 88). Eleven studies (21%) scored in the lowest possible quartile (0-25) of the CTAM, of which ten were quasi-experimental studies published between 1984 and 2015 and one was an RCT published in 2009. Only 13 studies (25%) scored at or above the cut-off of 65 suggested by Wykes et al. (2008) for adequate quality. These were all RCTs published between 1999 and 2016. For a further four RCTs published between 2001 and 2012, CTAM scores ranged from 61-64.

To gain a better understanding of particular methodological weaknesses across studies, mean scores on each of the six quality assessment subscales are presented in Table 2.



Table 2. Mean CTAM Subscale scores

CTAM Subscales	Items	Mean Score (SD)	Median	Maximum possible score
1. Sampling	Recruitment method	1.88 (.47)	2	10
	Sample size	2.88 (2.49)	5	5
2. Allocation	Random allocation	6.73 (4.74)	10	10
	Randomisation process described	1.21 (1.49)	0	3
	Independent randomisation	.35 (.97)	0	3
3. Assessment	Independent assessors	4.81 (5.05)	0	10
	Standardised measures	5.37 (1.24)	6	6
	Blinding of assessors	3.65 (4.86)	0	10
	Blinding process described	.06 (.42)	0	3
	Blinding verified	.06 (.42)	0	3
4. Control groups	TAU and/or group controlling for non-specific effects or other credible treatment	6.77 (4.87)	6	16
5. Analysis	Analysis appropriate to design	3.85 (2.13)	5	5
	'Intention to treat' analysis and/or appropriate handling of dropouts	5.15 (3.89)	4	10
6. Active treatment	Treatment adequately described and/or manual/protocol used	3.69 (2.35)	3	6
	Assessment of adherence to protocol	1.35 (2.24)	0	5

Most studies did not score highly in any CTAM domains, with particular weaknesses evident in recruitment methods, conducting and reporting randomisation and masking processes, definition of control groups and assessment of treatment adherence. Carer samples were usually recruited in connection with patients registered or receiving treatment at mental health clinics, and therefore most studies (n=49) received a rating of '2' for using convenience samples, while the remaining three studies received a score of '0' for using volunteer participants. Only 21 studies (40%) described the process of randomisation, with even fewer studies (n=6, 12%) reporting that randomisation occurred independently of the research team. Similar limitations were observed in the assessment process. While 25 studies (48%) reported using independent assessors, a smaller proportion (19 studies 37%) reported that assessors were blind to treatment allocation. Only one study described methods of masking (Kopelowicz et al., 2003) and one study reported verifying rater blinding at the end of the trial (Merinder et al., 1999). Eleven studies (21%) had poorly defined, non-equivalent control groups, receiving a score of 0/16 on the control groups subscale. Less than a third of studies (27%) assessed treatment fidelity.

Studies scored higher on CTAM items relating to sample size, random allocation, use of standardised measures, appropriate statistical analysis and treatment description. The large standard deviations on all these items, suggests notable variation between individual studies. However these results should be considered in view of the dichotomous scoring system, where studies not meeting an individual criterion were scored '0'. Thirty studies (58%) included over 27 participants per treatment group or based sample size calculations on a power analysis. All but 11 studies scored full marks on the use of standardised assessment measures. On the analysis subscale, 40 studies (77%) were rated as using statistical analyses appropriate to the study design and outcome measures, but only 22 RCTs included all participants as randomised in their analyses. Twenty-three studies (44%) provided some description of their treatment and used a treatment manual/protocol, of which three studies referred to other papers where treatments had been described,

(Calvo et al., 2014; Leff et al., 1989; Zhang, Yangling et al., 1998). However, 11 studies did neither, scoring 0 on this item.

### **3.5 Description of interventions**

Information about the content and structure of each group intervention were included in a qualitative synthesis. All interventions (except a yoga group) included a psychoeducational component, but were separated into different intervention categories based on the main approach / model, in keeping with categories reported in the literature (McFarlane et al., 2003). If studies compared two carer group interventions, only details of the intervention offered to the experimental group were reported. The group interventions comprised psychoeducation (n= 29), peer support (n=10), multiple family groups (n=5), relatives groups (n=5), web-based therapy groups (n=2) and a yoga group. All studies comprised carers of adults with schizophrenia, except for Calvo et al., (2014) where the group intervention was offered to parents of adolescents with early-onset psychosis.

#### **3.5.1 Psychoeducational groups**

The majority of studies evaluated psychoeducational groups (n=29), including 17 RCTs and 12 quasi-experimental designs. Interventions consisted of 1 – 24 sessions, each held for 1.5 – 2 hours on a weekly or fortnightly basis. The only brief psychoeducation group intervention comprised a single three-hour session (Cozolino et al., 1988). Some psychoeducation groups provided additional opportunities for group discussion (e.g. Zhang, Yangling, et al., 1998; Zhang et al., 1993), and enhanced peer support (Chien, 2008). The main components of the psychoeducation sessions were extracted from each study, and grouped into 13 categories for the purpose of this qualitative synthesis, as presented in Table 3.

*Table 3. Main psychoeducational components*

<b>Information about:</b>	<b>No. of studies</b>
Psychosis/schizophrenia	29
Antipsychotic medication and side-effects	25
Psycho-social treatments / rehabilitation	13
Relapse prevention	13
Community & professional resources/services	18
Other patient issues	6
Carers' mental health and self-care	11
Cultural issues/ stigma around mental illness	6
Promoting recovery within the family	19
Management/coping with patients' symptoms/behaviours	15
Problem-solving skills training	11
Communication skills training	11
Relaxation training	7

All studies included psychoeducation on psychosis/schizophrenia, including information on symptoms and aetiology. The majority of studies (n=25) also provided education on anti-psychotic medications, often including information on side-effects, medication compliance and long-term maintenance. A smaller number of studies dealt with psychological treatments for psychosis and psychosocial rehabilitation such as encouraging patient independence and employment (n=13). Some studies (n=13) provided information on relapse prevention, including recovery in psychosis, and recognising early warning signs. Over half the studies (n=18) also provided information about local community resources, professional services and mental health laws pertaining to patients, as well as support and social benefits available to carers. Some studies also included information about other patient issues, such as drug and alcohol abuse, (n=3) sexual relationships, marriage and family planning (n=3). Less than a quarter of studies (11 studies) addressed carers' mental health needs and self-care, and six studies dealt with cultural issues and stigma arising from mental illness. A larger proportion of studies focused on promoting recovery within the family (n=19), focusing on the role of family attitudes

towards patients, interpersonal problems and family issues, and low-stress home environments. Coping with patients' 'problem behaviours' or symptoms was covered by 15 studies. Some psychoeducation studies also included skills training components such as problem-solving and/or communication skills, including effective ways of expressing negative emotions to patients. Relaxation training and stress management were offered towards the end of a few groups.

### **3.5.2 Peer support groups**

Peer support groups, run as carer-led social alternatives to more professional-controlled mental health interventions, positioned carers as experts in the lived experience of caregiving in psychosis. Of the ten peer support groups included in the review, seven were RCTs by the same research group in Hong Kong (e.g. Chien and colleagues, 2005). The interventions, called 'mutual support groups', comprised 12-14 sessions, on a weekly or fortnightly basis. Sessions were peer-led, with one or two carers elected by fellow group members and trained in planning and leading group meetings and using the protocol. Peer leaders collaborated with a mental health professional to plan and run groups. This protocol specified six principles to guide group leaders in facilitating group work (Wilson, 1995), including personal disclosure, fostering dialectical processes, discussing taboo topics, engendering a sense of shared experience, encouraging peer support and providing opportunities for individual problem solving. Group members decided the focus for each session, guided by an intervention protocol, which specified five stages of peer support group development. Topics discussed in the five phases included cultural issues pertaining to mental illness (e.g. –stigma), patients' illness and effects on the family, carers' psychosocial needs in relation to caregiving, intense feelings regarding the patient and service provision, and illness management strategies, including medication, home management, mental health services and community resources. Groups also entailed coping skills for stressful situations, problem-solving skills and communication skills. These

components often included roleplays of carer-patient interactions, and carers were encouraged to practice techniques at home.

Other peer support programmes had varied formats. Perlick et al., (2011) offered a single session where carers watched a video about families coping with stigma, followed by a peer-led group discussion about self-stigma. Chou et al. (2002) offered a professional-led structured intervention comprising eight weekly sessions based on a modified version of the Caregiver Support Group Procedure Manual (Zarit et al., 1983). Discussions centred on information about the illness, problem-solving, coping and support. Mentis et al., (2014) refer to social support groups organized by non-governmental organisations, but do not report details of the intervention.

### **3.5.3 Multiple family groups (MFG)**

Five studies evaluated MFG (four RCTs and one quasi-experimental study), typically integrating psychoeducation with behavioural family therapy in a multiple family group format (McFarlane, 2002). Three studies in the review based their intervention on McFarlane's manual of MFG (1991), which recommends initial single-family joining sessions, followed by a day-long psychoeducation workshop, followed by fortnightly MFG meetings in the first year, and monthly meetings in the second year. Key components of each 90 minute MFG meeting include socialising around non-illness-related topics, reviewing recent concerns for each family, and group or single-family problem-solving on a particular issue. MFG offered by Hazel et al. (2004) and McDonnell et al. (2003) replicated McFarlane's manualised intervention, while Bradley et al. (2006) followed this manual with slight variations, providing MFG meetings for only a year. Calvo et al. (2014) provided an adapted intervention with single-family joining sessions, followed by 12 sessions of psychoeducation and problem-solving strategies, held separately for patients and carers. Liberman et al. (1984) who provided a shorter, less intensive intervention in a multiple family group format, spent the first two sessions providing psychoeducation

about schizophrenia, followed by four sessions devoted to training in four types of communication skills, and four sessions of family problem-solving.

### **3.5.4 Relatives groups**

Five RCTs evaluated relative groups. These were more loosely structured interventions, which generally integrated psychoeducational and peer support approaches. Following a brief psychoeducational component, the purpose of relatives groups was to consolidate gains from psychoeducation and increase opportunities for support. These groups were not usually protocol driven, and some studies used an open-group format. Mueser et al. (2001) offered 'supportive family management' which involved a three - six hour psychoeducational workshop followed by monthly open group meetings over two years comprising an educational presentation (on a topic chosen by group members), followed by group discussion and sharing of experiences. Szmukler et al. (2003) offered six individual family sessions of psychoeducation and discussion of the main problems faced by the carer, followed by twelve fortnightly relatives groups. Their groups began with a short talk on a particular area of interest, followed by opportunities to discuss carer problems in a supportive environment. Buchkremer et al., (1995) offered a relatives group with two main phases: psychoeducation for the first ten meetings followed by topic-centred personal therapy for relatives fortnightly for the rest of the year. Montero et al. (2001) offered two individual family psychoeducation sessions, followed by open weekly 90-minute group meetings over a year, aimed at enhancing coping and problem-solving strategies. Similarly, Leff et al. (1989) offered two individual family psychoeducation sessions followed by fortnightly group meetings which combined educational, behavioural, structural and systemic techniques (Berkowitz et al., 1981).

### **3.5.5 Web-based therapy groups**

Two American studies evaluated web-based interventions which included online psychoeducational materials and web-based therapy groups. An RCT by Rotondi et al. (2005) provided a 'Schizophrenia Guide' with informational materials on the intervention website, alongside three online therapy groups:

one for carers only, one for patients only, and one for all participants. Groups were facilitated by mental health professionals guided by a standardised facilitation protocol focusing on problem-solving. Similarly, a quasi-experimental study by Glynn et al. (2010) provided online psychoeducational resources alongside a weekly one-hour online group session facilitated by a psychologist who reviewed illness management issues and obstacles to problem-solving.

### **3.5.6 Yoga group**

Varambally et al., (2013) offered carers a stress-reduction package comprising yogic practice modules and meditative breathing exercises. Participants attended three 45 minute sessions per week for a month. Modules based on the 'Self-Management of Excessive Tension' (Nagendra & Nagarathna, 2008), were delivered by a trained yoga instructor.

## **3.6 Outcomes by type of intervention and measures used**

It was not possible to judge the effectiveness of interventions based on changes in a primary outcome measure, as most studies used several outcome measures (range 1-11), and less than half (n=19, 37%) identified a primary outcome measure. Treatment effectiveness is therefore described by type of intervention based on changes in each coded outcome category (Table 4). Studies were coded as 'effective' on each category if the relevant outcomes were significantly better in the experimental group as compared to control group(s), significant at the  $p < 0.05$  level. Studies were coded as 'inconclusive' if they had both effective and ineffective results on outcome measures falling within a single outcome category. Studies were also rated as inconclusive if they did not find significant changes in total scores on outcome measures, but reported significant differences only between subscale scores of the measure (e.g. Sota et al., 2008), if results were significantly better than control group(s) only at long-term follow-up, (e.g. Chien & Chan, 2013), if results were only significant when adjusting for variables such as expressed emotion, (e.g.



Cozolino et al., 1988; Shimodera et al., 2000) and if scores improved significantly within groups from pre- to post- test.

Table 4. Intervention efficacy by outcome category

Intervention	Efficacy	1	2	3	4	5	6	7	8	9	10
Psychoeducation	Effective	6	4	3	11	2	1	2		2	
	Ineffective	3	2	2	7	6	2	2	9	1	1
	Inconclusive	3	1		3	3	1	1	1		
	<b>N studies</b>	<b>12</b>	<b>7</b>	<b>5</b>	<b>21</b>	<b>11</b>	<b>4</b>	<b>5</b>	<b>10</b>	<b>3</b>	<b>1</b>
Peer Support	Effective				3					4	
	Ineffective			7							
	Inconclusive				1	1	2			1	
	<b>N studies</b>			<b>7</b>	<b>4</b>	<b>1</b>	<b>2</b>			<b>5</b>	
Multiple Family Groups	Effective					1					
	Ineffective				2		1	1		1	
	Inconclusive	1							1		1
	<b>N studies</b>	<b>1</b>			<b>2</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>	<b>1</b>
Relatives groups	Effective									1	
	Ineffective					2	1	1	2		1
	Inconclusive	1							3		
	<b>N studies</b>	<b>1</b>				<b>2</b>	<b>1</b>	<b>1</b>	<b>5</b>	<b>1</b>	<b>1</b>
Web-based therapy group	Effective										
	Ineffective				1	1	1				
	Inconclusive						1		1		
	<b>N studies</b>				<b>1</b>	<b>1</b>	<b>2</b>		<b>1</b>		
Yoga group	Effective										
	Ineffective										
	Inconclusive				1	1					
<b>Total Effectiveness %</b>		<b>43%</b>	<b>57%</b>	<b>25%</b>	<b>48%</b>	<b>18%</b>	<b>10%</b>	<b>29%</b>	<b>0%</b>	<b>70%</b>	<b>0%</b>

**Table key:** *1=knowledge acquisition, 2=attitudes/opinions/beliefs about illness, 3=need /use/ satisfaction with services, 4= burden, 5=psychosomatic health, 6=social support, 7=coping and self-efficacy, 8= quality of caregiving relationship, 9=family functioning, 10= family conflict*

### **3.6.1 Psychoeducational groups**

Of the 29 studies evaluating psychoeducational groups, the majority used outcome measures of carer burden (n=21). Other prominent carer-specific outcomes were knowledge of the illness (n=12), psychosomatic health (n=11), quality of caregiving relationship (n =10) and attitudes/beliefs about the illness (n=7). Group interventions appeared to be effective in 11/21 studies on carer burden, in 6/12 studies on carers' knowledge of illness, in 4/7 studies for change in attitudes and beliefs and in 3/5 studies on carers' need for and satisfaction with services. Only one study reported a negative effect of the intervention: Reid et al. (1993) found that carers in the psychoeducational group showed increased stress levels following the intervention. Psychoeducational groups were found to be largely ineffective on carers' psychosomatic health (6/11 studies), quality of caregiving relationship (9/10 studies) and sense of social support (2/4). Sixteen studies reported outcomes from follow-up assessments between 1- 24 months, indicating that improvements in knowledge (n=4) and carer burden (n=6) were maintained in the long-term, whereas there were mixed results for outcome category 5, with one study reporting improvements in psychological distress only at 6-month follow-up (Stengard et al., 2003) and two studies reporting that carers in all groups returned to baseline levels of stress and fear at 6 months (Birchwood et al., 1992; Smith & Birchwood, 1987). One study measured distress only at 24-months follow-up (Zhang et al., 1998). Three of the 16 studies found no significant improvements for psychoeducational groups at follow-up (Kopelowicz et al., 2003; Merinder et al., 1999; Carra et al., 2007), and results for Martin-Carrasco et al. (2016) and Paranthaman et al. (2010) remained inconclusive.

### **3.6.2 Peer support groups**

Seven of the ten peer support groups measured carers' use of and satisfaction with mental health and support services, but none effected significant changes on this outcome. However, 3/4 studies reporting carer burden outcomes and 4/5 studies reporting family functioning and satisfaction outcomes were found

to be effective. Most studies reported results from longer-term follow-ups ranging from one month to three years (n=8). Of these, four studies found that significant improvements were maintained in the peer support groups at follow-up, whereas three studies reported that significant changes in peer support groups were only found at 12-24 months follow-ups, leading to them being rated as inconclusive; however, these studies reported delayed significant improvements on social support outcomes (Chien & Chan, 2013; Chien et al., 2008), family functioning (Chien & Chan, 2013) and carer burden (Chien et al., 2006).

### **3.6.3 Multiple family groups**

Only one of the five MFG studies was rated as effective on an outcome category: Hazel et al. (2004) reported significant change on carer distress. Studies found no significant effects on carer outcomes relating to family environment (Calvo et al., 2014), burden (Bradley et al., 2006; McDonnell et al., 2003) and social support and coping (Hazel et al., 2004). Liberman et al. (1984) reported within-groups results in carers' knowledge of illness, quality of caregiving relationship and family conflict outcome categories, leading to an inconclusive rating.

### **3.6.4 Relatives groups**

Only one of the five studies offering relatives groups reported a significant improvement in carer-reports of family atmosphere (Buchkremer et al., 1995). One study was found to have a negative effect on carer outcomes: Mueser et al. (2001) found that carers' rejecting attitudes towards patients steadily worsened in the relatives group over the 2-year course of the intervention, compared to individual family therapy. Relatives groups were ineffective on carer outcomes relating to psychosomatic health (Montero et al., 2001; Szmukler et al., 2003), social support, coping and quality of caregiving relationship (Szmukler et al., 2003) and family conflict (Buchkremer et al., 1995). Two studies had inconclusive findings for expressed emotion, with different results for various EE dimensions: critical comments, hostility and overinvolvement (Buchkremer et al., 1995; Leff et al., 1989). Montero et al.

(2001) reported only within-groups results for carer knowledge of illness and EE, leading to an inconclusive rating. In terms of long-term follow-ups, Montero et al (2006) reported only patient results at 5-year follow-up, while Leff's results (1990) remained inconclusive at 2-year follow up.

### **3.6.5 Web-based therapy groups**

Of the two studies offering web-based interventions, Glynn et al. (2010) did not find significant improvement in distress, and Rotondi et al. (2005) found no significant effects on carers' illness-related distress and social support. Furthermore, Glynn et al. (2010) were rated as inconclusive on social support and quality of caregiving relationship outcomes as these involved within-groups comparisons.

### **3.6.6 Yoga group**

It was not possible to determine the efficacy of the yoga intervention compared to the waiting list control group, as Varambally et al. (2013) reported within-groups comparisons, leading to inconclusive findings on outcome categories related to burden and psychosomatic health.

## **3.7 Acceptability**

The total number of dropouts was used to gauge the acceptability of different group interventions. Most studies reported dropout rates ( $n=45$ , 87%), but reasons for drop-outs were not consistently described. An overall dropout rate for each type of group intervention was calculated on the basis of participants who dropped-out, in relation to the total sample size reported in these studies, presented in Table 5. Some studies reported zero dropouts, including 2 studies offering peer support groups, and 6 studies offering psychoeducational groups. Acceptability was highest for peer support groups (6%), followed by psychoeducational groups (11%) and web-based intervention (14%).

Table 5: Dropout rates for each intervention

<i>Intervention</i>	<i>Dropouts (n)</i>	<i>Overall sample size of studies reporting drop-outs (n)</i>	<i>Dropout rate %</i>
<b>Psychoeducational groups</b>	658	6043	<b>11%</b>
<b>Peer support groups</b>	49	895	<b>6%</b>
<b>Multiple family groups</b>	96	295	<b>33%</b>
<b>Relatives groups</b>	163	635	<b>26%</b>
<b>Web-based therapy groups</b>	6	42	<b>14%</b>
<b>Yoga group</b>	9	29	<b>31%</b>

### 3.8 Summary of results

Overall, the most popular carer outcomes used to evaluate group interventions were carer burden (29 studies, 56%), followed by carers' psychosomatic health (n=17, 33%) and quality of caregiving relationship (n=17). Group interventions were most effective on carer outcomes relating to family functioning (70% effective), attitudes and beliefs about the illness (57%) and burden (48%). The lowest effectiveness (0%) was found for three studies measuring family conflict outcomes, and 17 studies measuring quality of caregiving relationship. The most positive findings in terms of effectiveness and acceptability were for peer support groups and psychoeducational groups.

## **4. Discussion**

Intending to establish the impact of group interventions on carer outcomes, the current review sought to systematically outline the range of group interventions for carers in psychosis, and to assess the efficacy and methodological quality of the available evidence. Carers in psychosis comprise a severely neglected group (Kuipers, 2010), with support for carers not commonly available and difficult to implement (Eassom et al., 2014; Haddock et al., 2014). Group interventions are increasingly being offered and might effectively address the logistical and cost implications of enhancing support to carers. Fifty-two studies were reviewed, covering a range of group approaches, including psychoeducation (29 studies), peer support (10 studies), multiple family groups (5 studies), relatives' groups (5 studies), web-based therapy groups (2 studies) and a yoga intervention. Significant heterogeneity in the intervention strategies used, outcome domains measured and methods of analysing data, rendered the clinical interpretation of findings difficult. The review findings are discussed with reference to clinical implications and important areas for future research.

### **4.1 Overview of the evidence base**

#### **4.1.1 Outcome measures**

Overall, 103 different carer-specific outcome measures/scales were used by studies in the review, ranging from 1-11 carer measures per study. The Family Burden Interview Schedule (Pai & Kapur, 1982) emerged as the most popular choice (12 studies, 23%). Three other measures were used relatively frequently. Overall, seven studies used the Camberwell Family Interview (Vaugh & Leff, 1976). More specifically, among studies from Hong Kong / China, seven used the Family Assessment Device (FAD, Epstein et al., 1983) and eight used the Family Support Services Index (FSSI, Heller & Factor, 1991). The majority of measures were used only once (82, 80%). The outcome domain with the most idiosyncratic measures created specifically for the study was 'knowledge about schizophrenia', suggesting that the content of psychoeducation about schizophrenia might not be consistent between



studies, thereby impeding standardised assessment. Only 37% of studies in the present review identified a primary outcome measure or used only one outcome measure. Overall reporting of the rationale for selecting outcome measures was very poor. The large number of measures seen in the review is consistent with a trend to evaluate interventions with an excess of measures in studies with carers (e.g. Lobban et al., 2013; Sin & Norman, 2013) as well as in the broader schizophrenia intervention literature – criticised for a high ‘trial-to-new-scale ratio’ (Miyar & Adams, 2012). These factors precluded meaningful comparisons between studies in the present review, and it was not possible to evaluate the superiority of any particular intervention.

#### **4.1.2 Range of group interventions**

Over half the studies offered primarily psychoeducational interventions (29 studies, 56%). Chien and Norman (2009) criticise the narrow focus on psychoeducational approaches in the family interventions literature to the exclusion of alternative approaches such as peer support. Psychoeducation-based group interventions were heavily represented in the present review, perhaps reflective of a popular trend to evaluate psychoeducation strategies, as evidenced by the number of reviews on family psychoeducation studies since 2000 (e.g. Dixon et al., 2000; Murray Swank & Dixon, 2004; Jewell et al., 2009; Lucksted et al., 2012; Rummel-Kluge & Kissling, 2008; Sin & Norman, 2013).

The next most popular intervention was peer support groups (19%), mostly studies from Hong Kong and China published from 2002 onwards with similar formats. Fewer than 10% of studies offered either relatives groups (RG) or multiple family groups (MFG) respectively. A minority of studies also evaluated innovative ways of supporting carers in psychosis. Two seminal studies evaluating internet-based group interventions for carers in psychosis described the process of using web-based technology to overcome the challenges of supporting carers spread over a large geographical area. Another study offered carers training in yoga stretching and breathing exercises.

As psychoeducation was the predominant intervention offered by studies in the review, it was possible to analyse its main components. All psychoeducational interventions provided education about schizophrenia / psychosis, and most also included education about antipsychotic medication. Another common component was information relating to promoting patient recovery within the family, (e.g. creating low-stress home environments), congruent with the traditional goal of family interventions to improve patient outcomes through changing unhelpful family environments (Jewell et al., 2009). Half the psychoeducation groups included strategies to cope with patients' symptoms or difficult behaviours, similar to findings in a recent review of family psychoeducation in psychosis which reported good coverage of coping strategies (Sin & Norman, 2013). About 40% of interventions provided problem-solving skills and communication skills training respectively. Disappointingly, psychoeducation interventions had a limited focus on carers' mental health needs, self-care and experiences of stigma, despite these been highlighted areas of importance within the literature (Corrigan & Miller, 2004; Kuipers, 2001, 2010).

#### **4.1.3 Effectiveness and acceptability of group interventions**

Given the plethora of measures used to evaluate interventions, outcomes were categorised into ten outcome domains. Twenty seven studies (52%) reported statistically significant positive effects of the group intervention in at least one outcome category. Of these, 70% of studies found significant changes on family functioning, followed by 57% on carer attitudes and beliefs about the illness. Interventions were also effective in reducing burden (48%) and improving knowledge of the illness (43%). Overall, the least effectiveness (0%) of group interventions was seen on improving quality of caregiving relationship with the patient (17 studies), and reducing family conflict (3 studies), which could possibly be related to most group interventions excluding patients as participants (60%). A surprising finding was the limited effect of group interventions on improving perceived social support in carers (10%).

In terms of the effectiveness of specific intervention approaches, 50% of psychoeducational groups were found to be effective on carer burden, knowledge of illness, attitudes and beliefs about illness and need for/satisfaction with mental health services. However, psychoeducational groups had mixed findings relating to carers' psychological morbidity. One study found that psychoeducation had a negative effect on carers' stress levels (Reid et al., 1993). However, these findings should be interpreted with caution as they were based on a sample of five carers with baseline reports that the group was the *first* time they had spoken to non-family members about their relatives' illness. The authors suggest that the group could therefore have been a 'stressful and emotionally taxing' experience. In addition, long-term outcomes from three other studies indicated a return to baseline levels of stress and fear (Birchwood et al., 1992; Smith & Birchwood, 1987) or delayed improvement in distress (Stengard et al., 2003). While the beneficial effects of psychoeducation on knowledge acquisition have been widely acknowledged in the literature, it has less robust findings for improving carers' psychological morbidity and high expressed emotion (Sin & Norman, 2013).

Peer support groups showed significant positive benefits on carer burden and family functioning outcomes, which were largely maintained at long-term follow-up. This is in keeping with a review which found that peer support approaches reduce carer burden and distress (Chien & Norman, 2009). Interestingly, measures of carers' perceived social support were only used in two of ten peer support studies, whereas carers' satisfaction with services was evaluated in seven, once again raising questions about the relevance of outcome measures chosen to evaluate carer interventions. In these studies, benefits on social support outcomes were only seen at 12-24 month follow-ups. In addition, data supported the acceptability of group interventions for carers in psychosis, especially for peer support and psychoeducational approaches.

Only one of five MFG studies recorded a significant positive effect on carer distress. Here too, three studies employing the same intervention protocol (McFarlane, 1999) evaluated the intervention using measures in different

outcome categories, precluding any meaningful comparisons between them. Similarly, only one of five relatives groups reported significant benefits to family relationships and atmosphere. Drop-out rates were higher (26-33%) for MFG and relatives groups. In addition, one study found that carers' rejecting attitudes towards patients steadily worsened for those in the relatives group (Mueser et al., 2001). It is possible that participants in the less intensive 'supportive family management' programme comprising monthly relatives groups, did not receive adequate support. In contrast, carers in the 'applied family management' group, provided with monthly groups along with individual family therapy, showed lower levels of patient rejection. Ziller (1965) posits that open groups can have an expanded 'frame of reference', due to an exchange of diverse viewpoints which continue to change with group turnover. It is therefore possible that open-ended group structures (as in relatives groups) may not be as acceptable to carers (Leff et al., 1989), especially if they fail to adequately address carer needs around emotional support, skills training and illness management strategies (Greenberg & Greenley 1995).

Although web-based interventions were associated with high levels of carer engagement and acceptability, online therapy groups were not effective on carer outcomes of burden, quality of caregiving relationship and social support. Finally, the use of yoga as a clinically therapeutic intervention for carers, had positive but non-significant effects on psychological wellbeing, quality of life and burden, and relatively lower acceptability (31% dropout rate).

#### **4.1.4 Methodological quality of the evidence base**

An important aim of this review was to evaluate the methodological quality of group intervention studies. Using the CTAM as a quality assessment tool, the overall methodological rigour of studies was found to be low, further limiting the ability to draw firm conclusions about treatment efficacy. The low mean of 47 (range= 8-88) was similar to that stated in the review by Lobban et al. (2013), (mean=51.84, *SD*= 16.78, range = 15-87). Only 22-25% of studies scored above the cut-off for adequate methodology (Wykes et al., 2008) in the current review and Lobban's 2013 review. The relatively low figures

underscore the need for more rigorous methodology and meticulous reporting of trials in keeping with CONSORT (CONsolidated Standards of Reporting Trials) guidelines (Moher et al., 2003). Key methodological limitations highlighted in the present review pertained to conducting and reporting randomisation and masking, and a lack of well-defined control groups and assessment of treatment adherence. This is similar to Lobban's review, which outlined significant weaknesses in the literature including small sample sizes, poor definition of control groups, as well as lack of true randomisation, blind assessment and clearly specified primary outcomes. Thus there seem to be consistent methodological weaknesses in the psychosis family interventions literature. Of these limitations, blind assessment might be a crucial primary target for methodological refinement of carer interventions, given that it has been highlighted as the 'most influential methodological variable' accounting for heterogeneity among the effect sizes of CBT trials in psychosis (Wykes et al., 2008). In addition, this review contained a large number of international studies. Recent evaluations of the methodological quality of international studies in the psychosis literature highlight significant methodological weaknesses, cautioning that quality control should be emphasized as the evidence base expands globally (Miyar & Adams, 2012; Zhang et al., 2008). Rapid proliferation of research at the expense of methodological rigour can severely compromise the reliability of the evidence base.

## **4.2 Strengths and Limitations**

Based on a search of the literature and to the best of the author's knowledge, this is the first review of group interventions for carers in psychosis. Key strengths of the review included the use of systematic search strategies which identified studies evaluating a wide range of group intervention approaches, and the focus on carer outcomes to determine efficacy of the different groups. Another strength was the careful assessment of the methodological quality of the evidence base using a quality assessment tool which has been used in another review of family interventions in psychosis reporting carer outcomes (Lobban et al. 2013), enabling comparisons of overall quality ratings.

In addition, given the notable heterogeneity of studies in terms of study design, interventions, outcome measurement, analysis and methodological quality, the review favoured a narrative approach relying on systematic review and qualitative synthesis rather than a meta-analytic approach which can lead to misleading conclusions when studies differ widely across methodological and intervention domains (Ahlbom, 1993; Bailer, 1995). Lastly, including quasi-experimental studies in the review allowed for a wide-ranging exploration of group interventions for carers, not limited to RCTs. However, this could also be considered a limitation, as the Cochrane collaboration (2011) cautions that inclusion of both RCTs and uncontrolled trials in the same review can obscure interpretation of summarized findings.

The review presented a number of other limitations. Firstly, exclusion criteria relating to studies which did not have comparison/control groups meant that a number of studies offering group interventions and measuring carer outcomes were excluded from the review (e.g. Lowenstein et al., 2010; Maxwell et al., 2012), thereby limiting the scope of treatment description. Secondly, only one researcher reviewed studies for inclusion, which could contribute to biases in the study selection procedure. Thirdly, some studies were not clear whether they were reporting longitudinal outcomes from the same participants evaluated in an earlier study. For instance, Chien et al., (2005) and Chien et al. (2006), appeared to have identical study participants, but different measures were used in each study, which led to them being considered separate studies. However, this may have led to some duplication in the review data.

A fourth limitation concerned the use of the CTAM to assess the quality of studies. In developing a more robust tool to measure risk of bias in trials, the Cochrane Collaboration suggests that quality scales and checklists with resulting scores are not suitable for assessing clinical trials, especially because they often simultaneously assess aspects of trial conduct and quality of reporting, and “assign weights to different items in ways that are difficult to justify” (Higgins et al., 2011). In addition, some CTAM items were worded in ways which permitted subjective interpretation. For instance, the item relating to allocation asks the rater to judge whether there is ‘true’ random or

minimisation allocation, although 'true' allocation is not adequately operationalised. The Cochrane Collaboration (2011) recommends that judgements about random allocation depend on the reader's degree of certainty, based on the best available information, that comparison groups in the trial were established by random allocation, further stipulating that authors should explicitly state (usually by some variant of the term 'random') the allocation procedure used. Many studies in the review included the phrase 'randomly allocated' but did not go on to describe the randomization procedure, thus scoring lower on the CTAM which emphasizes the quality of reporting. This is similar to findings reported by Xu et al. (2008) who found that although most Chinese-based RCTs mention "randomization" in the title or abstract, only a minority described randomization methods, with similar patterns observed in relation to masking. In addition, 10 of the 16 quasi-experimental studies in the review scored consistently at a low level on many CTAM items relating specifically to a gold-standard RCT design (e.g. randomisation, 'intention to treat' analysis). This may have contributed to lowering the overall rating of methodological quality of the evidence base in this review.

### **4.3 Clinical Implications**

The review has several clinical implications for working with carers in psychosis. Findings indicate that group interventions are acceptable and effective in improving carer outcomes, especially relating to family functioning, attitudes and beliefs about the illness, burden and knowledge of the illness. The most reliable evidence emerged for the effectiveness and acceptability of psychoeducation and peer support groups, although the positive direction of results for MFG, RG, web-based groups and yoga intervention encourage continued investigations of the effectiveness of these different group modalities.

### **4.3.1 Format and structure of groups**

The review points to a wide variety of feasible group formats and structures, consistent with other reviews of family interventions highlighting the considerable variance in effective interventions for carers in psychosis (Lucksted et al., 2012). Interventions varied in terms of open and closed group formats, duration and number of sessions and additional support sessions offered. Conclusions could not be drawn about the most effective format, but, interestingly, in post-hoc analyses of an uncontrolled study by Sota et al. (2008), no significant differences were found in the benefits of a shorter versus longer psychoeducation group. It also seemed feasible for groups to accommodate large numbers of carers, with an average group size of about 14 carers, ranging from 6-40 participants per group. Most studies (60%) included only carers as group participants, while others included patients and carers together as group participants in all sessions (15%) or a few key sessions (10%). The remainder of studies arranged separate sessions for service users and carers.

In terms of intervention content, psychoeducation was a core element of all group interventions except the yoga group, either in a formal didactic setting, or using a more informal style of guided group discussions and peer-led education. Different programmes varied in their emphasis on behavioural family interventions and skills training, clinical rehabilitation of patients and enhancement of peer support and coping strategies. Overall, group content was broadly in line with current best-practice treatment guidelines (NICE, 2014; PORT, 2010) stipulating the inclusion of education about mental illness, family support, crisis intervention, and problem solving. Lucksted et al. (2012) posit that it is the 'core concepts' across variations which contribute to robust effects for some clinical outcomes. Findings of this review belie the notion that a single universal family programme can meet the needs of all carers, as numerous factors including culture, family and patient life cycle stages as well as phase and course of the illness may influence the effectiveness of carer interventions (Dixon et al., 2000).



Lastly, in terms of innovative intervention delivery methods, until further studies investigate the efficacy of internet-based interventions, online groups for carers should supplement, rather than replace, existing service provisions for carers (Álvarez-Jiménez et al., 2012, 2014).

#### **4.3.2 Facilitating group attendance**

Yalom (1995) highlights that group continuity is a necessary factor for the success of group therapy. Regular attendance therefore appears imperative to the attainment of treatment goals. Notable challenges facing clinicians conducting carer group interventions with carers will be optimising engagement and facilitating regular attendance. Several studies in the present review used particular strategies to facilitate attendance and reduce drop-outs. Extra provisions included arranging transport for carers, scheduling group sessions on weekends or after working hours, sending phone reminders before sessions, conducting sessions in a central location, as well as repeating sessions – allowing carers the choice to attend the most suitable group for them. For carers who missed group sessions, Abramowitz and Coursey (1989) provided individual sessions with the carer to cover the missed material. Berkowitz et al. (1981) also offered similar flexibility: sensitive issues that could not be covered in the group setting were dealt with as part of individual sessions within the home. In addition, Rotondi et al. (2005) set up computers and internet access in the homes of carers to facilitate access to online therapy groups. These findings suggest that local services should consult with carers in order to address common barriers to carers' engagement with services in order to plan additional provisions required to facilitate group attendance.

#### **4.3.3 Continued support for carers in psychosis**

Findings regarding the longer-term clinical impact of group interventions were unclear, and further research is required to understand the best way of supporting carers through the often enduring challenges of caregiving in psychosis. Research emphasises the need for carers to receive ongoing support, the role of enhanced problem-solving skills to cope better with

fluctuations in illness course (Dixon et al., 2001), and the importance of improving continuity of contact with carers (Burns et al., 2012). Furthermore, NICE guidance (2014) recommends that carer support should “*be available as needed*”. Many of the group programmes in the review were offered as one-off interventions, with little provided in the way of booster sessions. Only the programmes by Fiorillo et al. (2011) and Kopelowicz et al. (2003) included booster sessions following completion of the group, while Zhao et al. (2015) supplemented groups with 2-3 weekly home visits as part of their assertive community treatment (ACT) programme. Active encouragement of social network expansion in group interventions could improve opportunities for enhanced peer support in the long-term, potentially compensating for the short-term nature of most group interventions currently.

In terms of local service provision, health-care systems are under increasing pressure to provide cost-effective interventions in the ‘least intensive and smallest effective dose’ (Dixon et al., 2001). However, these demands should be balanced against evidence regarding optimal family intervention duration of at least 6-9 months (PORT, 2010). A recent review estimated that the intervention duration of successful psychoeducational programmes ranged from 16–18 hours over 8–24 weeks (Sin & Norman, 2013).

#### **4.3.4 Cultural adaptations**

This review highlighted a global trend in prioritising support to carers in psychosis (Sin & Norman, 2013). Studies from 18 countries evaluating treatment efficacy on carer outcomes, rather than solely in terms of patient relapse and symptom severity, speak to a growing recognition worldwide that carers require support in their own right. Over the last decade, research into carer group interventions has been developing internationally (Lucksted et al., 2012), with recent reviews commenting that psychosis intervention studies conducted in China and other non-English speaking countries are steadily increasing (Miyar & Adams, 2012).

In order to increase the acceptability of using carer intervention models cross-culturally and cross-linguistically, many international trials in the present review implemented cultural adaptations of evidence-based protocols and approaches originally developed in the USA or UK. For instance, Bradley et al. (2006) adapted their MFG intervention for Vietnamese-speaking carers, and liaised with a Vietnamese therapist for advice on appropriate cultural modifications. Similar adaptations were made for carers from China, Iran, Chile and Malaysia. Viewed collectively, these trials suggest that group interventions can be successfully adapted for, and are acceptable to, caregivers from diverse cultural backgrounds.

#### **4.4 Directions for future research**

This review highlights several priorities for future research into group interventions aiming to improve carer outcomes. Firstly, higher quality RCTs are required to extend the evidence base, taking account of the main methodological limitations identified in this review, especially in reporting randomisation procedures and using methods to reduce potential for bias, such as masking, and formally assessing treatment fidelity. Secondly, further research is needed to establish that group formats are an acceptable and effective way to implement carer interventions. It was noted that two group intervention studies (4%) found negative effects on carer outcomes relating to carer distress and rejecting attitudes towards the patient. Further research should be conducted to determine the important predictors of carers' response to treatment, and to further clarify which treatments and treatment components are appropriate for whom. Several studies considered levels of EE as potential moderators of response to treatment, and found that carers with lower EE scores had better treatment outcomes (e.g. Merinder et al. 1999; Sota et al., 2008). However, there remains a range of carer, patient and illness factors that may serve as helpful predictors about treatment responses.

Future research might also usefully focus on identifying the main active components of group interventions in order to clarify mechanisms of change, which remained unclear in the present review due to the multi-faceted nature

of the group interventions and the plethora of measures used to assess outcomes. A key related area for future research will be greater acknowledgment of the different types, and thus different aims, of group interventions for carers in psychosis, and for researchers to arrive at a consensus about the most valid, reliable and specific instruments to measure attainment of these goals. In a review of measures used in the caregiving literature, Harvey et al. (2008) point to the extensive range of structured measures used and stress that the outcomes selected should be those most relevant to the research. There is a crucial need for future studies to continue to measure carer-specific outcomes in the evaluation of carer interventions, but to be more focused in their selection of measures, and more specific in identifying a single, primary outcome.

Finally, given the growing number of international studies of group interventions for carers in psychosis, a useful focus of future systematic reviews would be the examination of global patterns and cross-cultural differences, for example in the dissemination and effectiveness of group interventions for carers in psychosis. This might also help to demarcate the features of successful cultural adaptations.

## **4.5 Conclusion**

This review was the first systematic evaluation of the range and effectiveness of group interventions for carers in psychosis, focusing exclusively on carer-specific outcomes. The findings suggest that various carer interventions in group formats have beneficial impacts on carer outcomes relating to family functioning, attitudes and beliefs about the illness, burden and knowledge of the illness. Current treatment approaches have a heavy emphasis on psychoeducation about schizophrenia and improving the family environment in order to support patient recovery. However, further development of group interventions which focus on carers' mental health needs and self-care is indicated. Overall, studies confirm the potential advantages of group interventions for carers in psychosis, but raise important caveats around methodological quality and consensus in measurement of carer-specific

outcomes. Future research requires better attention to potential sources of bias in trial conduct, better reporting of trial procedures and the use of specific pre-determined primary outcome measures.

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## 6. APPENDICES

### Appendix 1: Data Extraction Form

Author(s)	
Year	
Location	
Study Design	
N recruited	
N dropouts	
Recruitment method	
Allocation method	
Assessment method and blinding procedures	
Control group(s)	
Intervention offered	
Intervention description (main components)	
Group participants (carers/patients)	
Maximum participants per group	

No. of group sessions	
Format and structure of group	
Use of protocol/manual	
Assessment of treatment fidelity	
Carer-specific outcome measures used	
Primary carer outcome measure (if specified)	
Service user outcomes (if used)	
Clinically significant change on carer outcomes?	
Follow-up period and findings	
Analysis, including handling of missing data	
Special efforts made to facilitate group attendance	

## **Appendix 2: Clinical Trials Assessment Measure (CTAM, Tarrier & Wykes, 2004)**

### *Sample—two questions: maximum score = 10*

Q1: is the sample a convenience sample (score 2) or a geographic cohort (score 5), highly selective sample, e.g., volunteers (score 0)

*Convenience sample*—e.g., clinic attenders, referred patients or *Geographic cohort*—all patients eligible in a particular area

Q2: is the sample size greater than 27 participants in each treatment group (score 5) or based on described and adequate power calculations (score 5)

### *Allocation—three questions: maximum score = 16*

Q3: is there true random allocation or minimisation allocation to treatment groups (if yes score 10)

Q4: is the process of randomisation described (score 3)

Q5: is the process of randomisation carried out independently from the trial research team (score 3)

### *Assessment (for the main outcome)—five questions: maximum score = 32*

Q6: are the assessments carried out by independent assessors and not therapists (score 10)

Q7: are standardised assessments used to measure symptoms in a standard way (score 6), idiosyncratic assessments of symptoms (score 3)

Q8: are assessments carried out blind (masked) to treatment group allocation (score 10)

Q9: are the methods of rater blinding adequately described (score 3)

Q10: is rater blinding verified (score 3)

### *Control groups—one question: maximum score = 16*

Q11: TAU is a control group (score 6) and/or a control group that controls for non-specific effects or other established or credible treatment (score 10)

### *Analysis—two questions: maximum score = 15*

Q12: the analysis is appropriate to the design and the type of outcome Measure (score 5)

Q13: the analysis includes all those participants as randomised (sometimes referred to as an intention to treat analysis) (score 6) and an adequate investigation and handling of drop outs from assessment if the attrition rate exceeds 15% (score 4)

*Active treatment—three questions: maximum score = 11*

Q14: was the treatment adequately described (score 3) and was a treatment protocol or manual used (score 3)

Q15: was adherence to the treatment protocol or treatment quality assessed (score 5)

*Where the criterion is not reached for any question score = 0*

*Total score: maximum score = 100*



## *Service-Related Project*

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# **Evaluating the Effectiveness and Feasibility of Mindfulness groups for Voice Hearers in a Psychosis Support & Recovery Service**

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*Supervised by:*

*Dr Emma Harding*

## Abstract

**Objectives.** The aim of the study was to evaluate the effectiveness and feasibility of mindfulness-based groups for voice hearers within a support and recovery service for psychosis in South-East London.

**Design.** A non-randomised, uncontrolled repeated measures design was used to evaluate the effect of mindfulness-based groups on participants' psychological wellbeing, relationship with voices, voice control and distress and development of mindfulness skills.

**Methods.** Two mindfulness groups were run consecutively. The first group lasted 10 weeks, and service user feedback informed adaptations to the protocol for the second group, which ran for 12 weeks. The effect of mindfulness among 10 participants across the two groups was investigated.

**Results.** Attendance to the groups was sporadic. Participants' psychological wellbeing remained relatively stable. No significant changes were observed across secondary measures assessing participants' relationship to their voices, voice distress and control, and development of mindfulness skills.

**Conclusions.** Qualitative feedback from the first group indicated subjective benefits of mindfulness practice and group participation. Preliminary data suggests that mindfulness did not have an adverse effect on service users. However, to better understand the effectiveness of mindfulness groups in this service, individuals need to attend sessions regularly and home practice should be monitored. Group protocol may need to include more mindfulness practice. It may not be feasible to run mindfulness groups with more than 6 sessions in a service that supports individuals with chronic problems. Referral pathways into the group need to be further developed in order to optimize group participation.

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# **1. Introduction**

## **1.1 Auditory Hallucinations in Psychosis: Topography and Treatment**

A hallucination can be defined as “sensory experience, which occurs in the absence of corresponding external stimulation of the relevant sensory organ, has a sufficient sense of reality to resemble a veridical perception, over which the subject does not feel s/he has direct and voluntary control and which occurs in the awake state” (Anthony, 2004). Auditory verbal hallucinations or ‘voices’ are common among individuals with psychosis (Owens et al., 1989), with studies indicating prevalence rates between 40-60% in patients with schizophrenia (Slade & Bentall, 1988; McCarthy-Jones et al., 2014).

Hearing voices can be one of the most distressing aspects of psychosis (Wykes, 2004). Several cognitive models of psychotic symptoms suggest that it is a person’s appraisal of their voice(s) that mediates their psychological, emotional and physical reactions to the experience, rather than the voices themselves. Distress and disability in relation to voices can thus be conceptualised as arising from the individual’s relationship with the voice, rather than voice topography per se. In particular, negative appraisals regarding the uncontrollability and danger of voices can result in ‘perceived threat to physical or psychological integrity’ (Morrison, 1998). Birchwood and Chadwick (1997) found that malevolent interpretations of voices were associated with fear, anger and resistance to voices. Relationships with voices appraised as omnipotent and omniscient, are usually characterized by distress and subordination (Birchwood et al., 2000). Conceptualised within an ABC model then, it is not situations/experiences (Antecedents) that cause distress (Consequences), but rather the cognitive reaction (Beliefs) to them (Teasdale, Segal & Williams, 1995).

Research indicates that voices can persist in a significant proportion (25-50%) of service users on anti-psychotic medication (Pantellis & Barnes, 1996).

Treatment-resistant voices can be a significant concern to service users who hear voices, and various psychological treatments have been developed to help individuals cope with hearing voices (Wykes, 2004). The application of cognitive models of psychosis to clinical practice has led to the development of Cognitive Behavioural Therapy (CBT) for psychosis. Recent meta-analyses have concluded that CBT is an effective treatment for psychosis, with several studies demonstrating a reduction in symptoms (see Wykes et al., 2008, Zimmerman et al., 2005). However, Chadwick, Birchwood and Trower (1996) have argued that CBT for psychosis should not aim to control psychotic symptoms such as voices and delusional thoughts, but should instead focus on alleviating the distress associated with these experiences, i.e.- the 'C' in the ABC model.

Consequently, one important development in psychological therapies for psychosis has been the application of mindfulness-based approaches to voices (Thomas et al., 2014). These interventions focus less on cognitive change and attempt to address distress more directly by changing the relationship with voices through meditative practices in noticing voices, thoughts and feelings, and accepting them as passing events. Studies have shown the efficacy of acceptance and commitment therapy (Bach and Hayes, 2002) and mindfulness training (Chadwick et al., 2005) in people with psychosis.

## **1.2 Mindfulness**

Mindfulness is a meditative practice for consciously directing attention to the present moment in an accepting and non-judgemental manner. It is derived from Eastern spiritual meditation traditions, particularly Buddhism, (Kabat-Zinn, 1982) which convey that regular mindfulness practice can reduce suffering and engender positive qualities including awareness, insight, compassion and wisdom (Kabat-Zinn, 2000). The primary aim of mindfulness practice is to enhance awareness of present experience, by learning to bring attention back to moment-by-moment experience in the here and now. This typically involves using the breath as an "anchor" to ground attention and bring it back to the

present moment whenever one is distracted by worries, thoughts, or an overall lack of present awareness (Segal et al., 2002b, p.47)

In a Western context, mindfulness is taught as a set of skills independent of its spiritual origins, and this type of practice has been incorporated into several psychological interventions used widely across physical and mental health settings. In the 1970s, Jon Kabat-Zinn developed and offered a mindfulness-based stress reduction (MBSR) programme for people suffering from a number of health conditions, including chronic pain, heart disease, cancer etc. Subsequently, Segal, Williams and Teasdale (1995) combined MBSR with elements of CBT for depression into an 8-session group programme. This intervention, called Mindfulness-based cognitive therapy (MBCT), initially targeted at relapse prevention in people with recurrent depression, has now been applied to a number of psychiatric conditions (Sipe et al., 2012). The core principles of mindfulness practice are conveyed through MBCT (Segal, Williams & Teasdale, 2002, p. 92-93), including:

- *Concentration*: the ability to deploy and maintain attention on a particular focus is central to all other aspects of MBCT. This involves sustained, quality attention that is gathered and focused rather than dispersed and fragmented.
- *Awareness/mindfulness of thoughts, emotions/feelings and bodily sensations*: This is important because one cannot intentionally let go of unhelpful patterns unless first aware of them. A variety of experiential methods, including body scans, guided sitting meditation, mindful stretching, mindful walking and mindful breathing help to bring awareness to the present moment, thereby utilising processing resources that are required for the self-perpetuation of unhelpful patterns such as rumination.
- *Being in the moment*: Instructors can support a moment-by-moment awareness by giving instructions at the moment when participants need to act on them, rather than in advance.
- *Decentring*: a way of becoming aware of thoughts, feelings and bodily sensations, thereby intentionally facing difficult experiences and



discomfort which one might usually tend to avoid, (referred to as experiential avoidance).

- *Acceptance/non-aversion, nonattachment, kindly awareness:* “Acceptance of what is” counteracts the cognitive habit of avoidance, Daily exercises aim to increase non-judgmental awareness of thoughts, feelings and sensations, so as to foster the ability to see both the bad and the good of a situation in a wider perspective, and respond to the totality of the situation rather than reacting to just one fragment.
- *Letting go:* a key skill in preventing oneself getting into and stepping out of unhelpful cycles. It is a very important part of the body scan and mindfulness of the breath. People can find it difficult when their minds wander during practice, but being able to detect the wandering and return to the breath or the body is more important than staying on the breath/body all the time. Individuals are encouraged to allow thoughts and experiences (internal and external) to come and go naturally, and the outbreath is used as the natural vehicle in letting go.
- *“Being” rather than “doing”, non-goal attainment, no special state (of relaxation, happiness, peace, etc.) to be achieved:* Learning to be aware of one's mode of being – a form of metacognitive awareness – can give one the freedom to override habitual, over-learned, automatic patterns of cognitive-affective processing. Unhelpful patterns are part of the “doing/driven” mode, concerned with achieving defined end points and monitoring current state against “should” states. Having a single focus at any one time during mindfulness practice facilitates this mode.
- *Bringing awareness to the manifestation of the problem in the body:* can help withdraw processing resources from automatic unhelpful routines while still keeping the problem ‘in process’ by bringing awareness to bodily cues to stress.

Other psychological interventions that incorporate mindfulness principles and techniques include Dialectical Behaviour Therapy for borderline personality disorder (DBT; Linehan, 1993), and Acceptance and Commitment Therapy (ACT; Hayes et al., 1999). However, the most widely used and robustly

evaluated mindfulness-based psychological interventions (MBIs) are MBSR and MBCT. Empirical evidence has shown that MBIs can enhance wellbeing in comparison to control conditions, effectively reducing depressive symptoms (Strauss, Cavanagh, Oliver, & Pettman, 2014), risk of relapse for depression (Kuyken et al., 2008; Teasdale et al., 2000), anxiety symptoms (Davidson et al., 2003) and psychological symptoms in patients with cancer (Ledesma & Kumano, 2009). In addition, it is found to improve quality of life among depressed patients (Godfrin & van Heeringen, 2010), as well as reduce stress in a non-clinical population (Chiesa & Serretti, 2009).

### **1.3 Mindfulness and Psychosis**

A robust evidence base has supported the use of MBIs in the treatment of mood and anxiety disorders over the last two decades, fuelling a recent move to investigate the effectiveness of mindfulness for treating other psychiatric conditions including psychotic disorders. Most notably, Chadwick (2006) developed Person-based Cognitive Therapy (PBCT) which incorporates mindfulness into traditional cognitive therapy (CT) for psychosis, and can be conceptualised in a revised ABC model of distress, as shown in Table 1. In this model, three aspects of cognitive mediation together contribute to distress (Chadwick, 2006, p.13): meaning (central to a CBT understanding of distress), relationship to sensations, (mindfulness understanding of distress) and metacognition (common to both CT and mindfulness conceptualisations of distress). Since the distress to voices arises from the aversive reactions, the focus of mindfulness in PBCT is to focus decentered awareness on unpleasant psychotic sensations, e.g. – voices. Although voices experienced mindfully might remain unpleasant, the person is freed from the distress that arises from habitually reacting against them.

Table 1. *ABC model of distress*

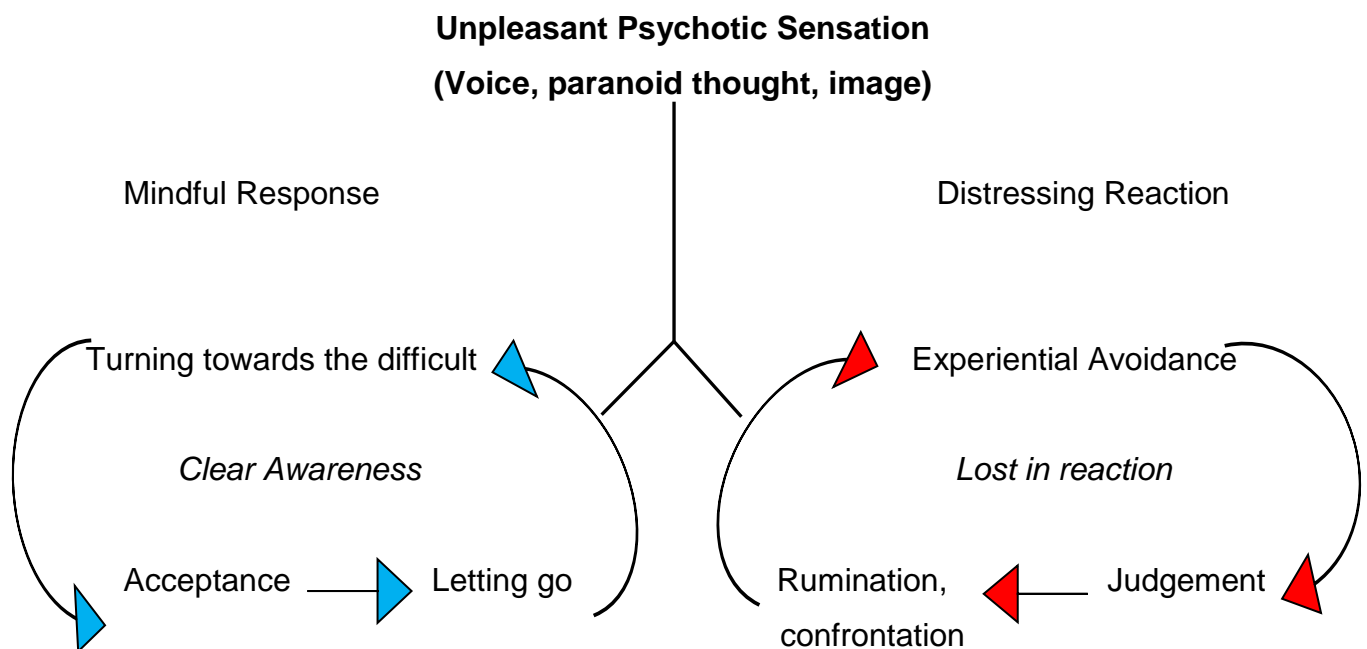
<b>Situation (Antecedents)</b>	<b>Cognitive Mediation (Beliefs)</b>	<b>Distress (Consequences)</b>
Situation and specific (psychotic) sensations	<ul style="list-style-type: none"> <li>• Meaning/appraisal</li> <li>• Relationship to sensations (avoidance, rumination, judging)</li> <li>• Metacognition</li> </ul>	<ul style="list-style-type: none"> <li>• Emotional experience</li> <li>• Behaviour</li> <li>• Bodily experience</li> </ul>

Thus mindfulness, as applied to psychosis, conveys a relational understanding of distress, i.e. – it is the type of reactive relationship to psychotic experience that causes distress. According to this model, in response to an unpleasant psychotic experience, a person experiences distress when he/she become lost in their reaction to the voice and thereby fails to develop a clear awareness of what he/she is experiencing (Chadwick, Newman Taylor & Abba, 2005). Reactive responses might involve experiential avoidance, rumination/confrontation, and negative judgments of the experience, the self or both (see Figure 1). Research indicates the use of these strategies in reaction to paranoid thoughts (Freeman, Garety and Kuipers, 2001) and voices (Birchwood and Chadwick, 1997).

On the other hand, a mindful relationship with experiences involves an awareness of these experiences while maintaining some distance and de-centering one's identity from them (Lau et al., 2006). Such a response to voices involves clear awareness and acceptance of voices as transient experiences that do not define the self and might not accurately reflect reality. This experiential practice of 'decentred awareness' (Segal et al., 2002b) and acceptance of experience in the moment is one of two key mechanisms by which mindfulness moderates distress and promotes wellbeing (Chadwick, 2006). The second mechanism is 'metacognitive insight', a term which describes the phenomenon of perceiving one's thoughts, emotions, and sensations as "events in the mind, rather than as direct readouts on reality" (Teasdale, 1999b, p. 147). This process is facilitated by the Socratic dialogue

following each mindfulness practice when clients reflect and share what was noticed about various sensations (including voices) and their reactions to the sensations, noting how their relationship to their voice impacts on emotional state.

Figure 1. *Model of mindfulness in psychosis (adapted from Chadwick, 2006, p. 51)*



Some studies point to the detrimental effects of meditation among people with psychosis (e.g.- Garcia-Trujillo et al., 1992; Kuijpers et al., 2007; Walsh & Roche, 1979). However, this evidence is based on single-case studies and the findings should be considered in light of the following limitations. Most studies provide limited information about the specific meditation techniques employed. Furthermore, participants were engaging in intensive meditation practice (i.e., involving up to 18 hours of meditation per day with prolonged periods of fasting and/or silence). In addition, they were attending open meditation retreats rather than practicing meditation within a clinical setting (Shonin et al., 2014).

However, there has been a growing evidence base supporting the utility of MBIs in psychosis. The first study to use mindfulness as a stand-alone group

intervention for psychosis (Chadwick, Newman-Taylor and Abba, 2005) comprised a 10-minute mindfulness practice tailored for people hearing voices, along with psycho-education and guided discovery, held over 6 weeks. Results showed significant pre-post improvement in wellbeing, as well as an increased ability to respond mindfully to distressing thoughts and images. A replication RCT by Chadwick, Hughes, Russell, Russell and Dagnan (2009) using a similar protocol over 10 weeks, found that although the experimental group showed pre-post improvement on the CORE and an increase in mindfulness of distressing thoughts and images, these results were not statistically significant compared to waitlist controls. However, a small-scale RCT by Langer et al. (2012) who delivered a mindfulness group intervention over 8 weeks to schizophrenic patients found significant improvements in the mindfulness group over waitlist controls in their ability to respond mindfully to distressing thoughts and images. Subsequently, a larger-scale RCT (Chien and Lee, 2013) found that compared to a treatment-as-usual control group, schizophrenic patients who received the mindfulness-based psychoeducation group intervention demonstrated significant long-term improvements in psychosocial functioning, psychotic symptom severity, and frequency of re-hospitalization.

Only one study to date has evaluated the effectiveness of a mindfulness-based group intervention for a population with chronic psychosis. Dannahy et al., (2011) developed a PBCT group protocol administered over 8-12 weeks to people with treatment-resistant and subjectively distressing voices. The protocol included a 10-minute mindfulness practice, followed by Socratic dialogue aimed at emphasizing the importance of accepting the voice hearing experience, and closely examining relationship with voices. The protocol also included cognitive components which helped participants identify and test out negative and positive self-schema, with a view to enhancing self-acceptance. Results showed that participants showed significant improvements in wellbeing, as well as distress, control and dependence on the voice.

The acceptability and benefits of using MBIs in psychosis are further supported by qualitative feedback from group participants. A qualitative grounded theory

analysis examined the experiences of participants with chronic, treatment-resistant positive symptoms (Abba, Chadwick, & Stevenson, 2008), in an intervention employing the same treatment protocol as Chadwick et al. (2005). Mindfulness was found to help participants centre in the awareness of psychotic experiences, allow psychotic sensations to move in and out of awareness without attempting to change them, and enhance their acceptance and non-judgmental awareness of self and symptoms. Another qualitative study evaluating the experiences of schizophrenic patients participating in an eight-week mindfulness intervention (Brown et al., 2010) found that mindfulness helped reduce psychotic symptoms as well as increase relaxation capacity, and change cognitive-attentional abilities. Ashcroft et al. (2012) found that participants of a mindfulness group in an early intervention psychosis service found the intervention acceptable and reported increased feelings of self-acceptance as well as empowerment by withdrawing from reactive responses to psychotic symptoms. This was consistent with findings from a recent small-scale qualitative study on patients with distressing voices (Dennick et al., 2013). In addition, qualitative analyses on the aforementioned PBCT groups found that participants benefitted through changes to beliefs about voices and strengthening of positive self-schema (Goodliffe et al., 2010), as well as through mindfulness principles and practice and orientating towards a symbolic sense of self (May et al., 2014).

## **2. Aims of the Study**

Mindfulness groups have been found to be useful with individuals experiencing psychotic symptoms (Chadwick et al., 2005, 2009). The Mindfulness for Voice Hearers groups aim to provide a different way of relating to voices for those whose voices have not abated with medication or other interventions. The main aim of the present study is to evaluate the experience of two mindfulness meditation groups for service users who hear distressing voices.

The present study has four specific aims:

1. To audit the effectiveness of mindfulness groups for voice hearers, by looking at changes in participants' clinical functioning following participation in mindfulness groups.
2. To assess whether participants have a changed relationship with their voices following mindfulness therapy.
3. To assess whether the mindfulness-based group interventions increase mindfulness.
4. To evaluate the feasibility of mindfulness groups for voice hearers in a Support and Recovery community mental health team in South-East London, by looking at patterns in attendance rates and data collection across the two groups run. Qualitative feedback will be collected from the first group about what aspects participants found helpful and less helpful, and their recommendations will be used to adapt the group protocol for the second group.

## **2.1 Hypotheses**

Improvements in participants' wellbeing and relationship with voice(s), voice distress and control, as well as acquisition of mindfulness skills are hypothesized. This will be evaluated by comparing participant scores before and after the Mindfulness group intervention on the following outcomes measures:

1. Clinical Outcomes in Routine Evaluation (CORE)
2. The Voice and You (VAY)
3. Kentucky Inventory of Mindfulness Skills
4. Voice distress and Voice control analogue scales

## **3. Method**

### **3.1 Service Context**

The Southwark Support and Recovery service is a Community Mental Health Team in the London borough of Southwark, which falls under the Psychosis Clinical Academic Group (CAG), and supports service users with chronic psychosis. In an attempt to improve support for people who hear voices, the service trialled two Mindfulness groups for voice hearers. The first mindfulness group ran for 10 weeks. Service user feedback was collected at the end of the first group, and group protocol was adapted to incorporate their suggestions. A second mindfulness group was run for 12 weeks using the adapted protocol.

### **3.2 Participants**

Group participants were recruited from service users in the Support and Recovery services at the Southwark Central, North-west, North-east and South teams, as well as the START team (Psychosis CAG). At the time of the groups, participants all met criteria for various psychosis diagnoses and were receiving standard psychiatric care, including medication. Inclusion criteria were that the individual had been experiencing voices for at least one year and found their voices distressing.

Participants were 23 individuals with subjectively distressing voices, referred to community mental health teams for people with chronic psychosis. A total of 11 participants were invited to participate in the first group. A total of 12 participants were invited to participate in the second group, of which 4 were “repeaters”, i.e. – participants from the first mindfulness group who wished to attend the second group.



## **3.3 Procedure**

### **3.3.1 Referral and assessment process for mindfulness groups**

Community Psychiatry Nurses, Social Workers and Clinical Psychologists in the stated teams were requested to refer eligible clients to the mindfulness groups for voice hearers. Upon referral, service users were invited to attend an individual assessment appointment lasting half an hour. Assessment for group participation comprised:

1. information that mindfulness was a new approach which was being trialled in the service to help people who hear voices
2. explanation of what mindfulness practice entailed
3. clarification of group expectations, in particular that attendance to the group was completely voluntary, and group participation did not involve talking about the past / traumatic experiences
4. opportunities to ask questions about the group, following which written consent was obtained, including to voice-record feedback at the end of the group.
5. administration of self-report measures for baseline data collection.

### **3.3.2 Mindfulness group session delivery**

Mindfulness training comprised weekly group sessions plus home practice with a guided meditation CD. In the first group, the group sessions ran for 10 weeks. Groups were closed, with each session lasting 90 minutes, including a 10 minute tea break. Group sessions were facilitated by one chartered clinical psychologist experienced in CBT for psychosis and mindfulness, and a trainee clinical psychologist. In addition, a handout was produced and distributed after each session, summarising the main discussion points. In the second group, the intervention comprised 12 weekly sessions, with each session lasting 120 minutes, including a 10 minute tea break. The content of group sessions was specified in a session-by-session protocol, adapted from a mindfulness-based group piloted by Dannahy et al. (2011). For the first group, the protocol also

included elements of 'Compassion Focused Therapy' (see Appendix 3), while the second group relied solely on material from the original Dannahy protocol. All other details relating to session delivery remained the same in the two groups.

Session 1 was spent discussing participants' hopes and concerns about joining the group and establishing the group's ground rules (confidentiality, sharing only what people are comfortable to talk about, respect for others' opinions). The premise of the group was then introduced, highlighting that the main aims were to reduce distress, explore the impact of voices, look at the relationship between the voices and the self, and practice a set of helpful mindfulness techniques. The rationale for practising mindfulness was then introduced through Socratic discussion of how people currently react to their voices and the impact of these strategies on how they see the self. Mindfulness was offered as a third way of responding to voices – an alternative to engaging or repressing voices. Participants were taught a ten-minute Mindfulness of the breath practice. This was followed by a Socratic discussion of participants' experience of Mindfulness and how voices impacted on practice. Recorded CDs of guided mindfulness practice were supplied to support practice. The usefulness of home practice was highlighted, but conveyed as voluntary. All subsequent sessions began with the 10 minute Mindful breathing practice led by clinicians, followed by Socratic discussion of the practice. This was followed by general discussion of the past week, including any difficulties with home practice. Therapists regularly checked participants' understanding of mindfulness, to promote awareness of mindfulness and clarify any misconceptions, such as the primary purpose of mindfulness being relaxation.

A concentrated chunk of cognitive work was undertaken in the second half of every session. This consisted of Socratic discussion on what has been learned about voices and the self. Session 2 introduced the ABC model, highlighting how beliefs about the power of voices influence painful and distressing emotional / behavioural consequences to voices. In sessions 3 and 4, the model was applied to individual experiences with voices, focusing on unhelpful beliefs people might have about their voices, especially regarding power. This

included making ratings of conviction in the belief, 'I have no control when the voices are active'. For homework, participants were asked to notice evidence which did not support these beliefs and record it in a data log form.

Belief challenging was introduced in session 5, with the facilitators noting down things participants had been able to do in the last week even when the voices were active. The belief, 'I have no control when the voices are active' was reframed as 'I have some control when the voices are active', and conviction in the former belief was re-rated. Subsequent sessions looked at the origins of negative self-schema (e.g. – childhood, trauma) and focused on building a positive core-belief statement (e.g. 'I am likeable') by gathering evidence to support this belief using another data log. In the final session, participants were asked to consider their goals for the next 6 months if things were to go as well as they hoped. Participants were encouraged to consider how skills learnt in the group might help them achieve their goals.

### **3.3.3 Service User involvement**

At the end of the first group, participants were asked to provide qualitative feedback about how useful they had found the group sessions and whether there were aspects that could have been done differently. The group protocol was adapted based on service user feedback and then implemented with the second group.

Service user feedback indicated that the mindfulness group was effective in many ways, and highlighted the following benefits of group participation:

1. Service users reported that they found the practice of Mindfulness a useful strategy to use in coping with their voices, and found they were able to practice it at home with the help of Mindfulness CDs given out in the group.
2. Service users were able to reference the discussion points covered in each session using the summaries of each session that were mailed to them. Feedback indicated that this was a helpful tool to keep track of what was going on in from session to session.

3. Service users indicated that they found it useful to think about the different kinds of relationships people have with their voices, and felt that this information was easy to remember because the facilitators used a creative enactment with a scarf to demonstrate the different ways in which people might relate to their voices.
4. Service users also found the group setting very useful to meet other voice hearers and to learn about ways in which people cope with voices. Some group members reported they were able to add these methods to their own repertoires of coping strategies. Service users indicated that it would be useful if this information was detailed in the session summaries.

Service user feedback indicated there was room for improvement in the following areas:

1. Service users reported that a lot of material was covered in a relatively short amount of time, and indicated that it might be better to extend the duration of each session.
2. Service users felt that some of the material was quite difficult to grasp, especially when mindfulness ideas were combined with elements of compassion-focused therapy, and these combined concepts were applied to understanding their relationship with their voices and their sense of self. It is possible that some of the material might have been too abstract and hard to apply to their difficulties with voices.

### **3.3.4 Adaptation of Group protocol based on service-user feedback**

In line with service user feedback, the following changes were implemented when running the second Mindfulness group:

1. The group ran for 12 weekly sessions rather than 10, to allow more time to deliver the protocol.

2. Each session had a duration of 120 minutes with a fifteen minute tea break, in order to deliver material at a slower pace that was easier to follow.
3. The session-by-session protocol focused exclusively on Mindfulness and cognitive work around power over voices and positive self-schema, as set out in the Dannahy pilot group protocol (2011). The protocol did not include any elements of Compassion-focused therapy. Rather, the group protocol was adapted to ensure that only small chunks of information were presented and targeted pieces of cognitive work were undertaken in each session.

Adaptations to the protocol were discussed with a service user consultant who had attended the first Mindfulness group, to ensure that the adaptations adequately reflected service user feedback.

### **3.4 Outcome Measures**

All participants were assessed on outcome measures at two time points: prior to the group beginning (Time 1), and at the final group session (Time 2). In group 1, qualitative data was also collected from participants at Time 2. Since the focus of the groups was not on symptom reduction per se but rather on general psychological wellbeing, the primary outcome measure was the CORE-10, which measures current psychological distress. Secondary measures evaluated changes in relationship with voices, voice-distress, voice-control, and development of mindfulness skills.

#### **3.4.1. Clinical outcomes in routine evaluation-10 (CORE-10)**

The CORE-10 is an abbreviated 10-item scale derived from the original 34-item CORE-OM (CORE-Outcome Measure), which measures current psychological global distress. The CORE-OM was developed for use in routine clinical practice, and evaluates four main areas: subjective well-being, life functioning, problems and risk. Responders rate how they have felt in the last

week. Item scores range from 0 to 4, with higher scores indicating higher psychological distress. The CORE has been validated with samples from both general and clinical populations, and is considered a useful outcome measure due to sound psychometric properties and good sensitivity to change (Evans et al., 2002).

### **3.4.2 The Voice And You (VAY)**

Since the group was aimed at providing people with a new way of relating to their voices, the VAY was administered to measure pre- and post- differences in interrelating between the hearer and his/her predominant voice. Relating is measured across four scales: voice dominance, voice intrusiveness, hearer distance and hearer dependence. The Voice and You (VAY : Hayward et al., 2008) comprises 28 items, with each item measured on a four-point Likert scale (0-3), generating the following range of scores for each scale: Voice Dominance, 0-21; Voice Intrusiveness, 0-15; Hearer Distance, 0-21; and Hearer Dependence, 0-27. The VAY has good internal consistency ( $\alpha > .75$  for all scales) and acceptable test-retest reliability ( $r > .7$  for all scales).

### **3.4.3 Kentucky Inventory of Mindfulness Skills (KIMS)**

Participants completed a self-report inventory which assessed the development of mindfulness skills. The KIMS (Baer et al., 2004) assess core mindfulness skills including observing, acting with awareness, and accepting without judgment. 'Observing' items measure the ability to notice various internal and external stimuli (e.g. - cognitions, bodily sensations, sounds, smells). 'Acting with awareness' items measure the ability to attend to and engage fully in one's current activity. 'Accepting without judgment' items measure the ability to allow the observed reality to be as it is without judging, avoiding, or changing it. The version of the measure used in this study comprised 31 items, rated on a 5 point Likert scale ranging from 1 (never or very rarely true) to 5 (almost always or always true). Each skill has the following range of scores: Observing (12-60), Acting with awareness (10-50), Accepting without judgement (9-45). High scores reflect more mindfulness. The measure has good reliability and validity (Baer et al., 2004), and has been

found to have to be sensitive to change among a clinical population participating in Mindfulness-Based Cognitive Therapy (Baum et al., 2010).

### **3.4.4 Voice-control and Voice-distress analogue scales**

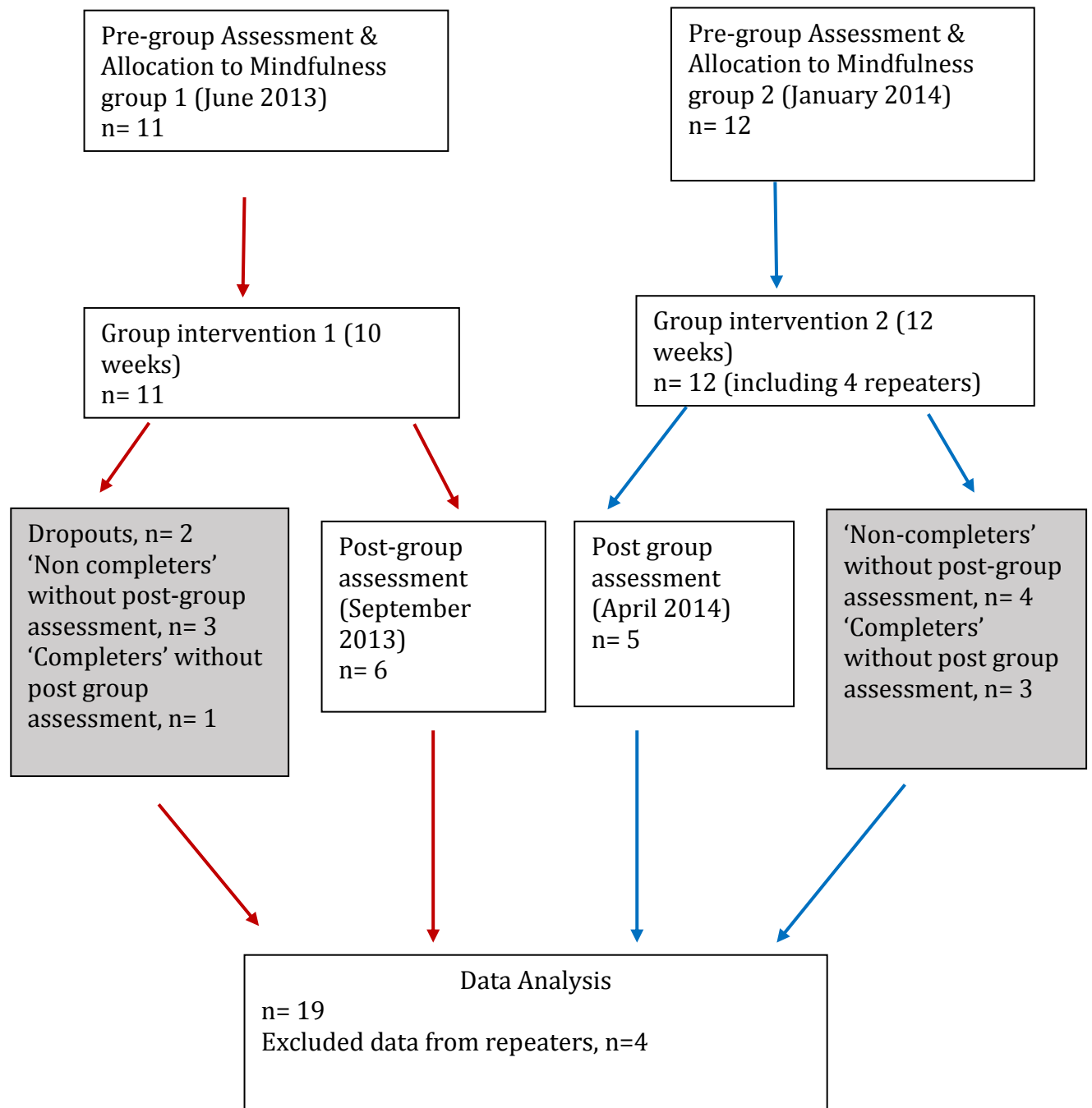
In the first group, it was thought that the above measures did not capture change in distress and control in relation to voices following group intervention. Therefore in the subsequent group, analogue rating scales of perceived control and distress in relation to voices were used to measure any changes in these areas. Analogue scales of subjective experience have been shown to be sensitive to these changes (Chadwick et al., 2000).

Consequently, in the second Mindfulness group, participants were asked to rate the perceived control voices had over them in response to the question: 'How much control does your voice have over you?' Ratings were given on a 10 centimetre analogue scale ranging from 0 (none at all) to 10 (total control over me). Participants were asked to rate the distress caused by their voices on a 10 centimetre analogue scale ranging from 1 (not at all distressed) to 10 (very distressed indeed).

## **3.5 Statistical Tests**

A total of 23 participants took part in the two Mindfulness groups: 11 participants in Group 1, and 12 participants in Group 2. Data from 19 participants was analysed: comprising 11 participants from the first group, and 8 participants from the second group. For the 4 repeaters, only data from Group 1 was included in the data analysis (see Figure 2). Post-group outcome measures were obtained from a total of 11 participants: 6 participants in the first group and 5 participants in the second group (including 1 repeater) who completed post-group assessment. Due to the small size of the sample from which completed measures were analysed ( $n=10$ ), non-parametric analyses were conducted.

Figure 2. *Flowchart outlining pathways through the study*



**KEY:**

- Group 1
- Group 2



## 4. Results

Results showed that participant outcomes from time 1 and time 2 remained relatively stable (see Table 2).

Table 2. Means and standard deviations on all outcome scales at time 1(pre-group) and time 2 (post-group)

Scale (min – max possible)	Time 1 – Pre group Mean (sd), n= 19	Time 2 – Post group Mean (sd), n=10
CORE-10 (0-40)	20.87 (6.6)	21.50 (6.7)
VAY Voice Intrusiveness (0-15)	8.08 (4.7)	9.13 (4.2)
VAY Voice Dominance (0-21)	13.29 (6.7)	14.00 (5.6)
VAY Voice Dependence (0-27)	8.54 (6.6)	10.75 (10.3)
VAY Voice Distance (0-21)	13.79 (3.8)	16 (3.8)
KIMS Observing (12-60)	38.07 (7.6)	39.60 (8.6)
KIMS Acting with awareness (10-50)	28.93 (5.8)	27.40 (7.3)
KIMS Accepting without judgement (9-45)	24.93 (6.8)	23.30 (8.3)

### 4.1 Primary Outcome: CORE-10

A Wilcoxon signed-rank test was conducted to evaluate whether group participants showed changes in psychological wellbeing following the mindfulness groups. The results indicated no significant difference,  $z = -.566$ ,  $p < .50$ . Of the 10 participants to complete this measure at time 1 and time 2, the direction of change in scores was positive for 4 people and negative for 4 people, whilst 2 people showed no change.

### 4.2 Relationship to Voices

#### 4.2.1 VAY

A Wilcoxon signed-rank test was conducted to assess any changes in participants' relationship to their voices, from time 1 to time 2. No significant changes were found in participants' voice intrusiveness, dominance, dependence or distance following the group intervention.

### 4.2.2. Voice Control and Distress

Participants in the second mindfulness group rated the distress caused by their voice and the level of control they felt the voice had over them, (see Table 3). The direction of change in the mean ratings was positive, with results indicating a decrease in distress and a decrease in control of voice over the individual. A Wilcoxon Signed rank test revealed no significant differences between time 1 and time 2.

Table 3. *Analogue ratings of distress and control of voices*

Scale (min-max possible)	Time 1 – Pre group Mean (sd), n= 12	Time 2 – Post group Mean (sd), n= 5
Voice - distress (0-10)	7 (2.9)	6 (4.4)
Voice - control (0-10)	6 (3.4)	4.8 (4.4)

## 4.3 Development of Mindfulness skills

Data from the Kentucky Mindfulness Inventory assessed whether people learnt three core mindfulness skills: observing, accepting without judgment and acting with awareness following the intervention. A Wilcoxon Signed rank test revealed no significant differences on any three skills following the intervention.

## 4.4 Attendance

Of the 11 participants in the first Mindfulness group, 6 people (54.5%) were considered ‘completers’, i.e. – they had attended 5 or more sessions, as well as pre-group assessment. Of the remaining 5 participants, 3 attended sporadically and 2 dropped out after one session. Among the 12 participants of the second Mindfulness group, 6 were considered completers (50%), and the rest attended sporadically, with no participant dropping out after one session. Mean attendance across the two groups was similar, with an average attendance of 5 sessions per group. However, attendance rates per session

fluctuated across both groups, although more sporadic in group 2 (see figures 3 and 4).

Figure 3. *Attendance rates per session for Group 1 (n=11)*

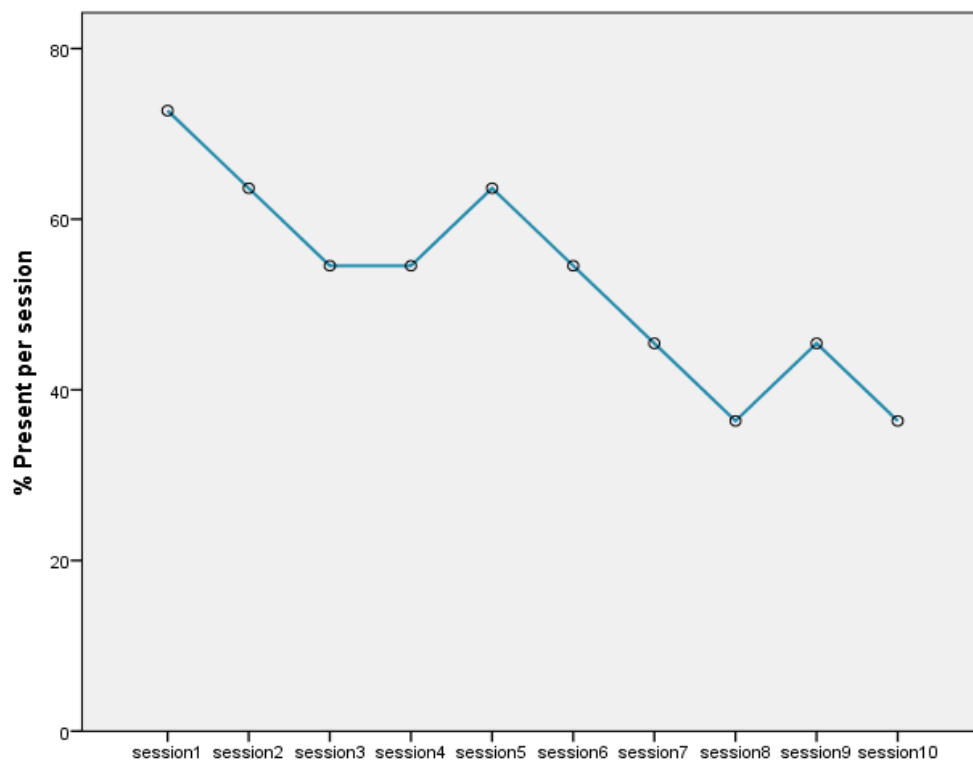
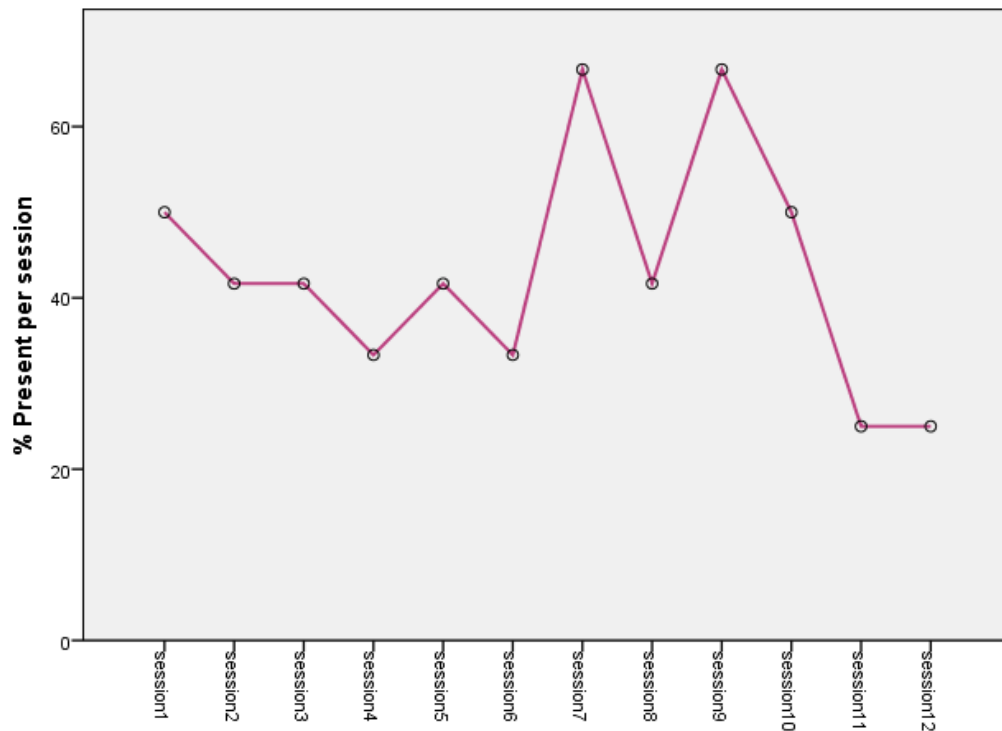


Figure 4. *Attendance rates per session for Group 2 (n=12)*



Gender distribution in the groups was skewed, such that group 1 consisted of 7 men and 4 women, and group 2 consisted of 8 men and 4 women. In group 1, it appeared that women attended a greater number of sessions than men. A one-tailed Mann-Whitney test indicated that women attended more sessions (Mdn= 7) than men (Mdn = 3), and this difference was marginally statistically significant ( $U = 5.5$ ,  $p=.07$ ). In this group, women attended between 6-10 of the 10 sessions ( $\geq 60\%$ ), whereas men attended between 1-8. Gender differences in attendance were not present in Group 2.

Table 4. *Total attendance*

<i>Attendance</i>	<i>Range</i>	<i>Mean (sd)</i>
<b>Group 1</b>	<b>1-10 sessions</b>	
Total (n=11)	1-10	5.27 (3.07)
Males (n=7)	1-8	4 (2.94)
Females (n=4)	6-10	7.50 (1.92)
<b>Group 2</b>	<b>1-12 sessions</b>	
Total (n=12)	2-11	5.17 (3.04)
Males (n=8)	2-11	5.25 (3.01)
Females (n=4)	2-10	5 (3.56)

In addition, a Spearman's correlation was conducted in order to assess the relationship between number of sessions attended and post-group CORE-10 outcome scores. No significant correlation between the number of sessions attended and primary outcome was found ( $\rho(10) = -.025, p=.47$ ).

## 5. Discussion

### 5.1 Effectiveness of groups

The main aim of the present study was to audit the effectiveness of a mindfulness-based group for voice hearers in a Psychosis Support and Recovery Service in South-East London. It was hypothesized that there would be improvements in participants' wellbeing and relationship with voice(s), voice distress and control, as well as development of mindfulness skills following the intervention. Descriptive analyses of baseline scores on the primary outcome measure – the CORE-10, indicate that participants referred for the groups fell in the moderate-severe clinical range of psychological distress. Wilcoxon signed-rank analyses showed no significant changes on this measure, with participants remaining in the moderate-severe clinical range following intervention. A similar trend was seen in all other outcome measures assessing changes in relationship to voices, voice control and distress, and development of mindfulness skills.

Although some limited evidence points to the potentially harmful effects of meditation among people with psychosis (e.g. - Yorston, 2001), the present study found no negative effects of mindfulness practice for people who hear voices, thereby replicating various recent findings from MBIs applied to people with psychosis (e.g. – Chadwick et al., 2009). Although no significant changes were found on the primary outcome measure of psychological well-being, these results mirror what is commonly seen among many service users in Psychosis Support and Recovery teams, where due to the chronicity and complexity of problems, people show limited change in measures of clinical functioning over time. Moreover, no significant changes were found on measures of voice relationship, voice control and distress, or mindfulness skills. Similar results have been found using mindfulness-based interventions among people with psychosis, for e.g. – Chadwick et al. (2009) and Valk et al. (2013) found no significant benefits on measures of psychological wellbeing, voice topography or mindfulness compared to the control condition. However, instead of taking this as evidence that a mindfulness-based approach in psychosis has no beneficial effects (Ruddle et al., 2011), it is important to consider factors which might have influenced outcomes in the context of a Support and Recovery service for long-standing psychosis.

Although several studies have highlighted the usefulness of mindfulness in early intervention for psychosis (Ashcroft et al., 2012) and demonstrated improvements in psychological wellbeing and acceptance of psychotic symptoms (Samson and Mallindine, 2014), early intervention for psychosis differs significantly from chronic psychosis. In the former group, people may not have persistent psychotic experiences, and are typically anxious about social and occupational functioning (Gumley & Schwannauer, 2006). Moreover, they may be earlier in the adjustment process to psychosis, and subsequently be more driven to develop skills to cope with psychotic experiences and feel less defeated by the condition. Chronic psychosis tends to be characterized by a distressing relationship with unremitting psychotic experiences, and understanding how this impacts upon the efficacy of mindfulness-based group therapy is important.

Only one study evaluating the effectiveness of mindfulness-based groups for chronic psychosis (Dannahy et al, 2011) has found significant improvements following intervention. In addition, qualitative information from grounded-theory analyses of mindfulness-based groups in chronic psychosis suggest that mindfulness can alter how people relate to enduring psychotic experience (Chadwick et al., 2005). Similar to the latter results, in the present study, participants' subjective reports of mindfulness indicated that it helped them let go of resistant/avoidant responses to voices, and brought about an increased sense of control. Thus, one of the main aims of the group was achieved, i.e.- to help participants change their relationship with their voices, especially to reclaim a sense of control over their own reactions to voices. This was apparent during the cognitive segments of the latter sessions, when participants' conviction ratings of the belief, 'I have no control when the voices are active' decreased, and conviction ratings in the belief 'I have some control when the voices are active' increased. In addition, for group 2, ratings in voice distress and control of voice indicated that changes in a positive direction occurred following the intervention.

Participants were also able to engage with the process of gathering evidence to support a positive self-schema, and the group provided an excellent network of support for those who could not gather evidence to positive schemas. For e.g. – one man who regularly attended the second group (11 out of 12 sessions) could not think of any evidence to support a positive self-schema. The therapists highlighted the fact that he had attended every mindfulness group, and the group reflected together on what qualities the man possessed which helped him to attend regularly. This seemed to be a rewarding experience for the man and he was able to arrive at a more balanced self-schema. Individual group participation experiences and subjective opinions as to the gains made through mindfulness suggest that this intervention requires further investigation among service users with chronic psychosis.

## 5.2 Strengths

Sparse evidence points to the negative effects of meditative practices in psychosis and advises against teaching meditation to people experiencing active psychotic symptoms (Deatherage & Lethbridge, 1975). However, these findings are based on single cases and include many forms of meditation and length of exposure (Chadwick et al., 2006, p.81). Consequently, the present study focused on teaching only one main mindfulness practice, and helping participants establish a mindful relationship with their voices within a therapeutic context rather than in a 'class' or retreat setting. It was thought that a supportive context facilitated by trained therapists would be conducive to participants attending to their distressing voices and reflecting about the process, while still feeling safe and contained by the therapeutic relationship. Evidence suggests hearing voices groups are successful when they provide a safe context for participants to share experiences (Ruddle et al., 2011). The two mindfulness groups succeeded in this regard, as made apparent in direct and indirect ways. Firstly, no participants from either group reported that mindfulness was having a detrimental effect on their wellbeing or voices. Rather, many participants reported that mindfulness helped them to relax and learn a new way of approaching their voices, and that they had found it useful to share their experiences of voices with others who had similar experiences. Secondly, a third of the participants from group 1 returned to participate in group 2, evidencing that they had found it helpful. In addition, the drop-out rate from the groups was low, suggesting that a mindful approach to voices was acceptable.

So as to minimize the likelihood of possible harmful effects among people with voices, the mindfulness practice was adapted in line with Chadwick's (2006) suggestions for using mindfulness in psychosis. Thus, only mindfulness of the breath was practiced in all sessions, and each practice was shortened to 10 minutes (from the longer 30-60 minute practises), which evidence suggests tends to be the upper threshold for people with psychosis (Chadwick, 2006). We also refrained from beginning sessions with a detailed mindful body scan as in typical MBCT and MBSR groups, as it was felt that it might be more



difficult for participants to ground their awareness if they were constantly shifting attention from one body part to another, especially for those whose psychotic experiences related directly to their bodies. For instance, one male participant who attended both mindfulness groups reported that he believed that the voices set off creatures moving around inside his body and he often scratched or shifted his limbs when he 'felt' them. Instead, practice began with a few seconds of gentle grounding of awareness across the whole body, noticing and letting go of any tension noticed in the body. Furthermore, in order to avoid long silences during which people might get caught up in their reactions to voices, the guided mindfulness practice involved therapists providing gentle prompts throughout the ten minutes. The mindfulness script was adapted to voice hearers (see Appendix 2), and included guidance about how to observe how voices might interrupt practice, while accepting their presence and labelling them as a voice, and noticing them pass away. Evidence suggests that listening to the therapist's voice guiding practice aids the process of decentering from the voices, struggle, rumination, etc. and helps in grounding oneself in the present moment experience (Chadwick, 2006). Lastly, in group 1, service user feedback was elicited in order to better understand what aspects of the group were helpful, and what aspects participants found less helpful. In adapting group protocol to incorporate this feedback, the second mindfulness group was more closely tailored to meet the needs of service users in this particular service.

Every effort was also made to bolster group attendance. Since service users found it difficult to maintain regular attendance during the first group, care was taken to call and remind participants of the group before every session of the second group. In addition, for both groups, session summaries were mailed on a weekly basis, including to clients who had not attended the week's session. This was done so that participants who had not attended a session would still be able to keep track of what they had missed and not feel anxious about coming along to the next session.

## 5.3 Limitations

The study has a number of limitations. Firstly, owing to the small sample size, it is difficult to draw conclusions about the effectiveness of the mindfulness-based group intervention. Although most participants' outcomes appeared stable following intervention, small changes in the direction of outcomes, whether positive or negative, could not be assumed to arise from the intervention itself rather than by chance. Secondly, it is possible that benefits from the intervention (for e.g. - the development of more positive self-schema) were facilitated by the group process or other factors extraneous to mindfulness. Qualitative feedback from Group 1 indicated that people had found the group format especially supportive and had drawn on each other's experiences to enhance their own coping with voices. Given the non-randomised, uncontrolled design of the study, it was not possible to delineate the positive effects of the mindfulness-based intervention from group participation. Future studies are warranted comparing mindfulness groups to support groups for voice hearers and waitlist control.

Furthermore, attendance to both groups was very sporadic. This too influenced data analysis and meant that no firm conclusions could be drawn about the impact of the intervention on outcomes. Clinical experience in psychosis Support and Recovery community services suggests that clients may find it difficult to keep track of scheduled appointments and attend regularly. In addition, a majority of clients tend to have chaotic lifestyles, and evidence suggests that this can hinder attendance among clients who hear voices (Meddings, 1998). A systematic review of treatment non-adherence in psychosis indicates that approximately one in four patients do not adhere with treatment programmes (Nosé et al., 2003). Moreover, the only other study to evaluate the effectiveness of mindfulness-based group interventions in long-standing psychosis (Dannahy et al., 2011) was conducted across NHS trusts located in relatively affluent Southern English counties. In contrast, the present study was conducted at a Support and Recovery service in one of the most socio-economically deprived boroughs of London. Evidence suggests that factors associated with non-adherence to treatment in psychosis include being

male, unemployed, and low social functioning (Nosé et al., 2003). Given that the latter two factors are more likely to be present among chronically ill people living in deprived communities, it is not surprising that group attendance was so sporadic in the present study. There was also a marginally significant gender difference found in Group 1, with female participants attending more group sessions than their male counterparts. In addition, attendance rates seemed to vary across the two groups. In group 1, attendance was relatively stable until session 6 (50-75% attendance), and then declined steadily for the last 4 sessions. In group 2 however, attendance was generally below 50%, with sudden inexplicable fluctuations. It is also notable that differences in attendance coincided with seasons: the first group ran in summer while the second group ran through the winter. Clinical experience points to poorer attendance to therapy appointments when days are shorter, darker and colder.

Another limitation of the study was the absence of any measure of home practice of mindfulness. Research suggests that time spent engaging in home practice of meditative exercises is significantly related to the degree of improvement in most facets of mindfulness, as well as well-being (Carmody & Baer, 2008). Although guided meditation CDs were provided for home practice, it was not clear how many participants regularly practised at home. This might have been a significant factor influencing the extent of change observed in individual outcomes.

Lastly, a crucial limitation of the present study was the missing outcome data for a large proportion of participants, due to data collection complications arising from sporadic attendance. Post-intervention outcomes were only collected from the minority of participants who made it to the final sessions of both groups. Although efforts were made to contact and arrange for post-outcome measures from those who did not attend the final group sessions, participants did not engage with this process – neither attending appointments arranged for post-group assessment, nor completing and returning measures mailed to them.

## 5.4 Feasibility and Service Implications

An important secondary aim of the present study was to evaluate the feasibility of running mindfulness-based groups for service users who hear voices in a Psychosis Support and Recovery service. Descriptive analyses of attendance across the two groups indicated that participants struggled to attend regularly, particularly in the second group as compared to the first group. In the first group, it appeared that participants were able to attend regularly until session 6, with attendance dropping for the last four sessions. It may not be feasible to run mindfulness groups with more than 6 sessions in a service that supports individuals with chronic problems. It might therefore be useful for the service to trial shorter mindfulness groups, i.e. - with a maximum of 6 sessions. This approach was used by Chadwick (2005) with good results.

It is also notable that the decline in attendance for group 1 coincided with the focus of the group protocol moving towards positive/negative self-schema and compassion. Qualitative feedback from group 1 indicated that some of these concepts were too abstract to grasp, and might have had less of an impact on participants' day-to-day struggles with voices. In order to better evaluate the effectiveness of mindfulness-based groups in this service, it might be important to increase the mindfulness practice component in the group protocol, as in the group protocol developed and employed by Chadwick et al. (2005) for people with psychosis, which included two 10-minute mindfulness practises followed by guided learning, one at the start of the session, and another one after the break. With more time in sessions spent focusing on mindfulness, it would be important for the cognitive aspects of the protocol to be more strictly focused, with discussions honing in on only one cognitive theme over the 6 sessions, such as power/control of voices which links in directly with mindful responses to voices. With such a specific focus, it is possible that participants might engage better both with the mindfulness practice and related cognitive aspects of the intervention.

Since this was a pilot study evaluating the first mindfulness groups to be run in the service, various team members were relatively unaware of what

mindfulness is, or whom the mindfulness groups targeted. Thus referral pathways into the group need to be further developed in order to optimize group participation. This may require psychologists who organise the groups attending team meetings of various teams and talking about mindfulness practice, its benefits and the planned groups. It would be an excellent idea to incorporate brief mindfulness practice into these sessions so as to give team members a tangible idea of what their clients will need to engage with in the groups. Team psychologists might be encouraged to regularly review new referrals with other team members to ascertain appropriateness of onward referral to mindfulness groups. It is important to help care-coordinators consider the demographic details of their clients, including factors such as living circumstances, employment, family support, engagement with individual therapy, etc. before referring to the groups, as these factors can have a significant impact on group attendance among a highly distressed and chronically unwell population. It is crucial to highlight to care coordinators that mindfulness groups require a certain level of commitment from service users, since regular practice both at sessions and at home can crucially impact on the clinical efficacy of the intervention.

To foster engagement of service users with mindfulness, it would be a good idea to organise one-session mindfulness taster groups for service users who hear voices, with a view to introducing the model and practice of mindfulness. It might be useful to also incorporate a brief video of past group participants talking about their experiences of the mindfulness group. Care-coordinators could be asked to signpost their clients who hear voices to these taster sessions. Service users who liked their experience in the taster session could themselves “opt in” to future mindfulness groups, by putting their name on a list of interested service users. For clients who are unable to attend these taster sessions, it might be a good idea to include a brief mindfulness practice in the initial assessment interview. After explaining to service users what mindfulness entails, a short mindfulness practice would help to socialize them into the practice. In addition, this meeting should also include a Socratic exploration of any concerns regarding attendance or joining a group. Such efforts might render service users more informed to decide whether they would

like to participate in the group, thereby motivating them to attend sessions regularly once they chose to participate in the group. It would also be a good idea to provide mindfulness booster sessions once a month for participants of previous mindfulness sessions, to review how they have been able to continue with mindfulness practice after the groups, and to once again engage them in mindfulness practice.

Another crucial aspect of feasibility relates to the selection of the most appropriate outcome measures and the collection of outcome data at various time points in the study. Firstly, although the measures in the present study were reliable and valid, an important issue to be considered is whether the outcome measures could have been influenced by non-specific factors other than the intervention. This is particularly relevant among service users who face chronic mental health problems alongside significant socio-economic challenges. For instance, measures of psychological wellbeing might not shift greatly due to various life circumstances or stressors that individual group members are facing. Furthermore, in the present study, no measures adequately addressed the crucial process question of whether the intervention helped participants to respond mindfully to their voices. Measures independently considered relationship with voices, as well as development of mindfulness skills, but future studies should use an idiosyncratic measure to look at the specific impact of mindfulness on voices, (e.g. - Chadwick et al. 2005). All participants should also fill out a brief questionnaire about the extent of home practice they engage in, so as to gain a better understanding of the level of their mindfulness practice outside sessions, and to evaluate whether this has an impact on outcomes. Secondly, in order to prevent missing data, it should be explicitly stated to participants that they will be asked to fill out some questionnaires at various time points: baseline, post-intervention, and follow-up. The present study did not collect measures at follow-up; however, future studies could attempt to collect follow-up data from all group participants at booster sessions. For participants who drop out, a questionnaire should be devised and administered to understand their reasons for dropping out. For participants who miss post-intervention and/or follow-up assessment, it would be useful to liaise with care-coordinators to find out when their clients will be attending an appointment with them, and request service users to stay an

extra 15 minutes after their regular appointment to fill out the questionnaires. Although this might consume important clinical time, it is crucial to obtain complete outcomes in order to better evaluate the effectiveness of the intervention.

In a critical review of the literature on MBIs for severe mental illness, Davis and Kurzban (2012) highlight that the approach seems to increase feelings of self-efficacy and reduce symptom-associated distress as well as psychiatric hospitalizations for individuals with psychotic disorders. In the present study qualitative feedback indicated that the mindfulness-based group interventions were acceptable to participants and conveyed various benefits. Although these benefits were not captured by formal outcome measures, it is important to address issues affecting feasibility and to re-run these groups. A major reason for conducting a pilot study is to be able to perform a sample size calculation for a larger study based on initial data for the primary outcome measure (Lancaster et al., 2004). The variance of baseline data from 19 participants across the two groups on the CORE-10 can be used for sample size calculations for a larger study evaluating the effectiveness of a mindfulness-based group intervention for service users who hear voices in this service.

## 6. References

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## 7. APPENDICES

### Appendix 1 – Outcome Measures

#### CORE-10 CLINICAL OUTCOMES IN ROUTINE EVALUATION

IMPORTANT – PLEASE READ THIS FIRST

This form has 10 statements about how you have been OVER THE LAST WEEK.

Please read each statement and think how often you felt that way last week.

Then tick the box which is closest to this. Over the last week...

		Not at all	Only occasionally	Sometimes	Often	Most/ all of the time
1	I have felt tense, anxious or nervous	0	1	2	3	4
2	I have felt I have someone to turn to for support when needed	0	1	2	3	4
3	I have felt able to cope when things go wrong	0	1	2	3	4
4	Talking to people has felt too much for me	0	1	2	3	4
5	I have felt panic or terror	0	1	2	3	4
6	I made plans to end my life	0	1	2	3	4
7	I have had difficulty getting to sleep or staying asleep	0	1	2	3	4
8	I have felt despairing or hopeless	0	1	2	3	4
9	I have felt unhappy	0	1	2	3	4
10.	Unwanted images or memories have been distressing me	0	1	2	3	4

Total (Clinical Score\*)

\* Procedure: If all items completed, add together the item scores. If some questions left blank, add together the completed item scores then divide by the number of questions completed to get the mean score, and multiply by 10 to get the Clinical Score.

## Kentucky Inventory of Mindfulness Skills

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes your own opinion of what is generally true for you

1	2	3	4	5
Never or very rarely true	Rarely true	Sometimes true	Often true	Very often or always true

\_\_\_ 1. I notice changes in my body, such as whether my breathing slows down or speeds up

\_\_\_ 2. When I do things, my mind wanders off and I'm easily distracted

\_\_\_ 3. I criticise myself for having irrational or inappropriate emotions

\_\_\_ 4. I pay attention to whether my muscles are tense or relaxed

\_\_\_ 5. When I'm doing something, I'm only focused on what I'm doing, nothing else

\_\_\_ 6. I tend to evaluate whether my perceptions are right or wrong

\_\_\_ 7. When I'm walking, I deliberately notice the sensations of my body moving

\_\_\_ 8. I drive on 'automatic pilot' without paying attention to what I'm doing

\_\_\_ 9. I tell myself that I shouldn't be feeling the way I'm feeling

\_\_\_ 10. When I take a shower or bath, I stay alert to the sensations of water on my body

\_\_\_ 11. When I'm reading, I focus all my attentions on what I'm reading

\_\_\_ 12. I believe some of my thoughts are abnormal or bad and I shouldn't be thinking that way

\_\_\_ 13. I notice how foods and drinks affect my thoughts, bodily sensations and emotions

\_\_\_ 14. When I do things, I get totally wrapped up in them and don't think about anything else

\_\_\_ 15. I make judgements about whether my thoughts are good or bad

\_\_\_ 16. I pay attention to sensations, such as the wind in my hair or the sun on my face

- \_\_\_17. I don't pay attention to what I'm doing because I'm daydreaming, worrying or otherwise distracted
- \_\_\_18. I tend to make judgements about how worthwhile or worthless my experiences are
- \_\_\_19. I pay attention to sounds, such as clocks ticking, birds chirping or cars passing
- \_\_\_20. When I'm doing chores, such as cleaning or laundry, I tend to daydream or think of other things
- \_\_\_21. I tell myself that I shouldn't be thinking the way I'm thinking
- \_\_\_22. I notice the smells and aromas of things
- \_\_\_23. I intentionally stay aware of my feelings
- \_\_\_24. I tend to do several things at once rather than focusing on one thing at a time
- \_\_\_25. I think some of my emotions are bad or inappropriate and I shouldn't feel them
- \_\_\_26. I notice visual elements in art or nature, such as colours, shapes, textures or patterns of light and shadow
- \_\_\_27. When I'm working on something, part of my mind is occupied with other topics, such as what I'll be doing later, or things I'd rather be doing
- \_\_\_28. I disapprove of myself when I have irrational ideas
- \_\_\_29. I pay attention to how my emotions affect my thoughts and behaviour
- \_\_\_30. I get completely absorbed in what I'm doing, so that all my attention is focused on it
- \_\_\_31. I notice when my moods begin to change



## **The Voice and You (VAY)**

### **PLEASE READ THIS BEFORE YOU START**

The statements listed here are the sorts of feelings and attitudes which people sometimes have about or towards the voices they hear. Please read each statement carefully and indicate, by ticking the appropriate column, the extent to which you think it applies to you in relation to your predominant voice.

Try to be completely frank and honest about yourself. Avoid answering the way you would like to be or the way you would like others to think of you, rather than the way you really are. Try as far as possible, to place your ticks in the "Nearly always true" and "Rarely true" columns. The two middle columns are really for if you cannot make up your mind.

#### **Please state -**

Your age: .....

Sex: M / F

Duration of voice hearing experience (years) .....

Diagnosis: (if relevant) .....

Are you currently taking anti-psychotic medication? Yes / No

	<b>Nearly always true</b>	<b>Quite often true</b>	<b>Some- times true</b>	<b>Rarely True</b>
1. My voice wants things done his/her way				
2. My voice helps me make up my mind				
3. I prefer to keep my voice at a safe distance				
4. My voice makes hurtful remarks to me				
5. My voice does not let me have time to myself				
6. I have a tendency to look up to my voice				
7. When my voice gets too close to me, it makes me feel uneasy				
8. My voice constantly reminds me of my failings				
9. My voice dislikes it when I exclude him/her by showing an interest in other people				
10. I allow my voice to take control of me				
11. I feel I have little to offer my voice				
12. It is easy for my voice to change my mind				
13. My voice does not give me credit for the good things I do				
14. My voice tries to accompany me when I go out				
15. I feel deserted when my voice is not around				
16. I try to hide my feelings from my voice				
17. My voice tries to get the better of me				
18. My voice dislikes spending time on his/her own				
19. My voice's judgment is better than mine				
20. I do not like to get too involved with my voice				
21. My voice makes me feel useless				
22. I need to have my voice around me a great deal				
23. I don't like my voice to know what I am				

thinking				
24. I have difficulty letting go of my voice				
25. My voice tries to make me out to be stupid				
26. My voice finds it hard to allow me to have time away from him/her				
27. I have a great need to talk to my voice				
28. I don't wish to spend much time listening to my voice				

## Analogue Rating Scales

What is your experience of the voice(s) you hear?

Please rate your experience by putting a cross on each line below to show how much control your voices seem to have and the amount of distress they cause you.

How much control does your voice have over you?

0-----10  
None at all Total control over me

How distressing is your voice?

0-----10  
Not at all distressed Very distressed indeed

## **APPENDIX 2: Mindful Breathing Guided Meditation Script**

Posture: feet on floor, hands on lap, sitting still, eyes closed, or open if too difficult...

1. It is easy to get locked into our minds, lost in our thinking, so we will start by bringing awareness into our bodies. Bring your awareness to points to the soles of your feet on floor. Really connect with the sensations in this place in your body - temperature, pressure, tingling.
2. Notice how these sensations are constantly changing, moving, coming and going. Nothing stays in awareness for long
3. We will gently move our awareness around the body – becoming aware of the sensations in your tummy, in your shoulders, releasing any tension you find there, in your hands, and in your face, letting go of any tension we are holding.
4. Now bring your awareness gently to the sensations in your body as you breathe in and as you breathe out. Find that place in your body where the sensations of breathing in and out are noticeable and comfortable. This might be rise and fall of abdomen or chest, or it might be noticing cool air coming in at tip of your nostrils and warmer air leaving as you breathe out.
5. Don't try to change or control your breathing in any way. Acceptance begins with the breathing. We are practising being fully aware of each in-breath, each out-breath, just as it is. Focusing on the breath and notice that you are alive in this moment.
6. We are not trying to force our attention to stay on the breathing. What you will find is that your awareness will move naturally to sounds, thoughts, feelings, and images. In mindfulness we allow this to happen. We see if we can observe sounds, thoughts, feelings pass or fade without reacting to them, each time allowing our awareness gently to return and rest again in the sensations of breathing in and breathing out.
7. Thoughts, and images come and go just like the sensations in our feet, and in our body. If you can, see what it is like to watch thoughts, and images, come and go, maybe like trains in a station. Think about being an observer watching the process of what is going on in your mind.
8. They may come back again a few moments later - each time we become aware of thoughts or images, we allow them into awareness, accept that they are there, and watch them pass without reacting, without being stirred by them, without being lost in them.
9. Remembering that we are not trying to get rid of thoughts or images or feelings, we are not trying to create an empty mind. If your mind is calm, that is fine; if your mind is jumbled and busy, see if you can accept that and watch how thoughts, feelings, images come and go.
10. We are practising being aware of whatever we experience in each moment, accepting each experience without reacting to it.
11. Often we find we're lost maybe reacting to feelings, difficult thoughts, images emotions. If that happens, don't worry, we all get lost like this. Notice how it feels to be lost in struggle. Notice how it feels to let go of

worry, struggle, judgement, and to rest your awareness in the next in-breath.

12. When you become aware of a difficult experience it can help to note or label it silently in your mind – voice, thought, image, feeling - and watch it pass or fade. Labelling helps us to remain fully aware of what we are experiencing.
13. You may find yourself judging a thought or a voice. Maybe judging yourself as a person for having the thought or experience. Maybe judging mindfulness – what is the point of it? Am I doing it right? Is this practice better or worse than the last one? If this happens, note silently to yourself 'judging' and see if you can let go of judging, notice how it feels to let go.
14. Notice the struggle that might be going on in your mind. Think about letting go and releasing yourself from the struggle.
15. For the last minute, if we can we will try and accept whatever comes into awareness, whether it is pleasant or unpleasant, and watch it fade or pass without reacting.

## Appendix 3: Compassionate Mind Training

### Compassionate Mind Training

Aim: To develop self-directed warmth, soothing, reassurance and self-liking in response to a setback or failure.

Rationale: Insecure attachment can lead to other people being viewed as a source of threat. People often strive to avoid criticism and rejection (evaluative concerns). Self-blaming / self-criticism / and striving to meet evaluative concerns can emerge as safety behaviours, especially when blaming others would increase threat (from abuse etc) so are linked to safety and protection though increasing sense of threat. When things go wrong for people they fear the consequences if they are criticised / rejected / neglected. They become self-critical and are unable to self-reassure. These reactions to threat are understandable, not our fault and not easily controlled.

Formulating self-criticism: early trauma (Emotional memories make it hard to feel safe), internal / external basic fears are responded to with basic safety strategies / behaviours / beliefs (e.g. blaming self, putting others needs first, not trusting others, trying to please or avoidance). These have unintended consequences – e.g. feeling isolated, not being taken seriously, working too hard which people then attack themselves for.

Process:

1. Imagery can put people in touch with the feeling associated with memories
2. Understand development of safety strategies as conditioned emotional responses and planned strategies / meta-cognitive beliefs to cope with / avoid external and internal threats – this is not one's fault!
3. Learn compassionate acceptance and empathy for the origins and use of safety strategies
4. Recognize our multiple subsystems (e.g. to flee / attack / seek approval) that can conflict – these different parts try as best they can to help cope but none sees the whole self.
5. Develop compassionate imagery and mindful ways of attending to and working with fears and safety strategies.
6. 'It is understandable why I feel like this and attack myself because my basic fear has always been that...'

Introducing compassionate mind training

1. Not 'taking on' self-criticism in the sense of undermining it
2. Explore fears behind it
3. switch perspectives to a compassion focused mentality - ?reduce self to self hostility
4. Empathy for one's own distress
5. Psychoeducation re attachment theory – humans are dependent on the good feeling of others towards them – absence of this denotes threat so our emotional minds try and protect us using strategies that become automatic. Though understandable these can prevent us from changing and be harmful
6. Brainstorm how protection-safety strategies might work – e.g. avoidance, anger

Imagine own ideal of caring, compassion flowing from the self to others, direct it towards self.

Rationale for imagery:

When hungry our brains will respond to seeing a meal by stimulating stomach acids. But they will also react to an internal image of a meal. Someone criticizing us activates our stress system. Inner critical voices can do the same. People being kind and understanding stimulates a soothing system. So maybe internally generated soothing images should stimulate this system in times of stress.

Write self compassionate letters – therapist guides to become more compassionate.